

# **EXHIBIT E**

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

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IN RE: ETHICON, INC., MASTER FILE NO. 2:12-MD-02327  
PELVIC REPAIR SYSTEM MDL NO. 2327  
PRODUCTS LIABILITY JOSEPH R. GOODWIN  
LITIGATION U.S. DISTRICT JUDGE

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THIS DOCUMENT RELATES  
TO ALL WAVE 5 AND  
SUBSEQUENT WAVE CASES  
AND PLAINTIFFS:

General re Prolift+M,  
Prosima, TVT-O and  
TVT-Exact matter

Monnica Reyes  
Case No. 2:12cv06141  
Shirley Terrebonne  
Case No. 2:12cv07779

Jodi Valverde  
Case No. 2:12cv07999

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VOLUME II OF DEPOSITION OF MARSHALL SHOEMAKER, M.D.  
PURSUANT TO NOTICE OF DEPOSITION  
Taken on Behalf of Plaintiffs

DATE TAKEN: July 22, 2017  
TIME: 8:07 a.m. - 11:09 a.m.  
PLACE: Holiday Inn Express, 19751  
South Greeno Road, Fairhope,  
Alabama

Examination of the witness taken before:

Lynn Robinson-Dykes, CCR  
GOLKOW LITIGATION SERVICES  
Ph - 877-370-3377 Fax - 917-591-5672  
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Marshall Shoemaker, M.D.

<p style="text-align: right;">Page 261</p> <p>1 APPEARANCES 2 FOR THE PLAINTIFFS:</p> <p>3 RESTAINO LAW, LLC 4 1011 S. Josephine St. 5 Denver, CO 80209 6 303-839-8000 7 BY: JOHN M. RESTAINO, JR., ESQUIRE 8 D.P.M., J.D., M.P.H. 9 jrestaino@restainollc.com</p> <p>10 FOR THE DEFENDANTS:</p> <p>11 BUTLER SNOW, LLP 12 1020 Highland Colony Parkway 13 P.O. Box 6010 14 Ridgeland, MS 39158-6010 15 601-948-5711 16 BY: JORDAN N. WALKER, ESQUIRE 17 jordan.walker@butlersnow.com</p> <p>18 19 20 21 22 23 24</p> <p>18 LYNN ROBINSON-DYKES, CCR 19 COURT REPORTER</p>	<p style="text-align: right;">Page 263</p> <p>1 Study" 342 2 40 Schimpf reference: "Sling Surgery for 3 Stress Urinary Incontinence in Women: A 4 Systematic Review and Metaanalysis" 360 5 41 Bjorn Holdo study: "Long-Term Clinical 6 Outcomes with the Retropubic Tension-Free 7 Vaginal Tape Procedure Compared to Burch 8 Colposuspension for Correcting Stress 9 Urinary Incontinence" 383 10 42 Study by Kurkijarvi: "Reoperations for 11 Female Stress Urinary Incontinence, a 12 Finnish National Register Study" 384 13 43 Position Statement issued by AUGS and SUFU 14 from 2016 386 15 16 17 I, Lynn Robinson-Dykes, Commissioner 18 and Court Reporter, certify that on this date, as 19 provided by the Federal Rules of Civil Procedure, 20 there came before me at the Holiday Inn Express, 21 19751 Greeno Road, Fairhope, Alabama, on July 22, 22 2017, commencing at 8:07 a.m., MARSHALL 23 SHOEMAKER, M.D., witness in the above cause, for 24 oral examination, whereupon the following proceedings were had:</p>
<p style="text-align: right;">Page 262</p> <p>1 INDEX 2 3 DEPOSITION OF MARSHALL SHOEMAKER, M.D., 7/22/2017 4 5 EXAMINATION INDEX 6 BY MR. RESTAINO ..... 264 7 BY MR. WALKER ..... 370 8 BY MR. RESTAINO ..... 395 9 10 EXHIBIT INDEX 11 30 Maher, Cochrane 2016 study 264 12 31 Milani reference: "Trocac-guided Mesh 13 Repair of Vaginal Prolapse Using Partially 14 Absorbable Mesh: 1 Year Outcomes" 278 15 32 Milani reference: "Medium-Term Clinical 16 Outcomes Following Trocar-Guided Mesh 17 Repair of Vaginal Prolapse Using Partially 18 Absorbable Mesh" 280 19 33 Zyczynski study 291 20 34 de Tayrac reference: "Basic Science and 21 Clinical Aspects of Mesh Infection in 22 Pelvic Floor Reconstructive Surgery" 299 23 35 Klinge, et al. reference: "Foreign Body 24 Reaction to Meshes Used for the Repair of Abdominal Wall Hernias" 304 36 Nolfi reference: "Host Response to Synthetic Mesh in Women with Mesh Complications" 311 37 Thames, Ong reference: "The Myth: In Vivo Degradation of Polypropylene-Based Meshes" 321 38 Email: Ethicon Mesh .07226481-Ethicon (Burkley) response to Clavé paper re degradation, March 2012 336 39 Brubaker: "Adverse Events Over Two Years after Retropubic or Transobturator Midurethral Sling Surgery: Findings from</p>	<p style="text-align: right;">Page 264</p> <p>1 (THIS DEPOSITION WAS TAKEN PURSUANT TO THE 2 FEDERAL RULES OF CIVIL PROCEDURE. READING 3 AND SIGNING BY THE WITNESS IS RESERVED.) 4 5 MARSHALL SHOEMAKER, M.D., 6 was previously sworn and testified as 7 follows: 8 EXAMINATION 9 BY MR. RESTAINO: 10 Q. Okay. Good morning, Dr. -- 11 A. Good morning. 12 Q. -- Shoemaker. Welcome back. 13 I'd like to start the day with 14 basically close to where we finished yesterday as 15 we continue to talk about prolapse, and that is 16 the Maher, Cochrane 2016 study that's titled 17 "Transvaginal Mesh or Grafts Compared with Native 18 Tissue Repair for Vaginal Prolapse (Review)," and 19 I will have this marked as next. 20 (Defendant's Exhibit Number 30 was 21 marked for identification.) 22 MR. RESTAINO: 23 30. 24 MR. WALKER:</p>

<p style="text-align: right;">Page 265</p> <p>1 All right.</p> <p>2 MR. RESTAINO: .</p> <p>3 Q. Do you need a copy of it?</p> <p>4 A. I have it.</p> <p>5 MR. RESTAINO:</p> <p>6 Okay. I just made -- and what I'm</p> <p>7 making -- that's where I put it. I just made --</p> <p>8 Jordan, for the record, again, instead of</p> <p>9 printing out the hundred-and-something pages,</p> <p>10 what I've done is the cover page, and then I</p> <p>11 realized I didn't delete two pages of the table</p> <p>12 of contents, and then there is the initial page</p> <p>13 with the abstract starting on the bottom and then</p> <p>14 page -- they call page 2.</p> <p>15 MR. WALKER:</p> <p>16 Got it.</p> <p>17 MR. RESTAINO:</p> <p>18 Q. And I'm really, Doctor, just going to</p> <p>19 address your attention to page 2.</p> <p>20 A. Got it.</p> <p>21 Q. Now, you see right at the top of the</p> <p>22 page, they talk about awareness of prolapse of</p> <p>23 one to three years was less likely after mesh</p> <p>24 repair? Do you see that, sir?</p>	<p style="text-align: right;">Page 267</p> <p>1 an expert?</p> <p>2 A. The data that -- as they quantified the</p> <p>3 data, there were some criteria that made it low</p> <p>4 quality. It wasn't a big enough study -- it must</p> <p>5 have not been a big enough study. There's</p> <p>6 different things that would make it low quality.</p> <p>7 Q. Okay.</p> <p>8 A. It just may not have been available</p> <p>9 more than the fact that it's a bad study.</p> <p>10 Q. Okay. And, in fact, the second to --</p> <p>11 underneath absorbable mesh versus native tissue</p> <p>12 repair --</p> <p>13 A. Right.</p> <p>14 Q. First of all, absorbable mesh is some</p> <p>15 of the other types of mesh that we'll be talking</p> <p>16 about today; is that correct?</p> <p>17 A. Right. Yes.</p> <p>18 Q. And you see at the bottom or the one,</p> <p>19 two, third sentence there again, recurrent</p> <p>20 prolapse on examination was less likely in the</p> <p>21 mesh group, and at the end it says low quality</p> <p>22 evidence once again --</p> <p>23 A. Right.</p> <p>24 Q. -- correct?</p>
<p style="text-align: right;">Page 266</p> <p>1 A. Right.</p> <p>2 Q. And do you see that there is --</p> <p>3 afterwards, they talk about the relative risks</p> <p>4 and the 12 randomized controlled trials, and they</p> <p>5 state moderate quality evidence?</p> <p>6 A. Yes.</p> <p>7 Q. And they do that each time, don't they?</p> <p>8 They rate the evidence as to whether it's -- or</p> <p>9 as they state here, moderate quality or they say</p> <p>10 weak or poor in some places; correct?</p> <p>11 A. Yes.</p> <p>12 Q. Or low quality?</p> <p>13 Okay. Now, you were asked yesterday</p> <p>14 about one aspect of it. I think it's the one,</p> <p>15 two, third paragraph. Which forgive me if I'm</p> <p>16 wrong, but I think you were asked by defense</p> <p>17 counsel about recurrent prolapse on examination</p> <p>18 was less likely after mesh repair, and there is a</p> <p>19 relative risk of 0.40. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Now, do you see at the end of it, it</p> <p>22 states low quality evidence?</p> <p>23 A. Yes.</p> <p>24 Q. And what does that indicate to you as</p>	<p style="text-align: right;">Page 268</p> <p>1 A. Correct, and that's for absorbable</p> <p>2 mesh.</p> <p>3 Q. Yes.</p> <p>4 A. Okay.</p> <p>5 Q. Now, underneath there, the authors</p> <p>6 write conclusions; correct?</p> <p>7 A. Correct.</p> <p>8 Q. And you see the first paragraph says:</p> <p>9 "While transvaginal permanent mesh is associated</p> <p>10 with lower rates of awareness of prolapse, repeat</p> <p>11 surgery for prolapse, and prolapse on examination</p> <p>12 than native tissue repair, it is also associated</p> <p>13 with higher rates of repeat surgery for prolapse</p> <p>14 or stress urinary incontinence or mesh exposure</p> <p>15 (as a composite outcome), and with higher rates</p> <p>16 of bladder injury at surgery and de novo stress</p> <p>17 urinary incontinence. The risk-benefit profile</p> <p>18 means that transvaginal mesh has limited utility</p> <p>19 in primary surgery. While it is possible that in</p> <p>20 women with higher risk of recurrence the benefits</p> <p>21 may outweigh the risks, there is currently no</p> <p>22 evidence to support this position."</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes, you did.</p>

<p style="text-align: right;">Page 269</p> <p>1 Q. Now, the second to the last sentence,  2 they write: "The risk-benefit profile means that  3 transvaginal mesh has limited utility in primary  4 surgery."  5 As a gynecologist, what is primary  6 surgery?  7 A. The first surgery that's done for  8 prolapse.  9 Q. So if a patient came in that you  10 operated on who has a prolapse after her surgery,  11 would that be a secondary surgery?  12 A. The second -- that would be a secondary  13 surgery.  14 Q. Okay. Okay. Thank you.  15 And then the next paragraph, they  16 write: "Limited evidence suggests that  17 absorbable mesh may reduce rates of recurrent  18 prolapse on examination compared to native tissue  19 repair, but there was insufficient evidence on  20 absorbable mesh for us to draw any conclusions  21 for other outcomes. There was also insufficient  22 evidence for us to draw any conclusions regarding  23 biological grafts compared to native tissue  24 repair."</p>	<p style="text-align: right;">Page 271</p> <p>1 still available have not been evaluated within a  2 RCT. In the meantime, these newer transvaginal  3 meshes should be utilized under the discretion of  4 the ethics committee."  5 Did I read that correctly?  6 A. Yes, you did.  7 Q. And do you have an ethics committee at  8 your hospital?  9 A. Yes.  10 Q. Do they advise you on what mesh you  11 should be using?  12 A. I have not had that -- been experienced  13 -- I have not had the experience to have to talk  14 to the ethics committee about mesh.  15 Q. Okay. All right. So let's move on to  16 your expert report, sir.  17 A. Okay.  18 Q. And --  19 MR. WALKER:  20 Are we done with Cochrane?  21 MR. RESTAINO:  22 We are.  23 A. Are we on Prosima or where are we?  24 MR. RESTAINO:</p>
<p style="text-align: right;">Page 270</p> <p>1 Did I read that correctly?  2 A. Yes.  3 Q. First, the biological grafts, what are  4 they?  5 A. That would be either xenografts or  6 allografts. They are either from pig fascia, pig  7 bladder. The other one could be cadaver. If  8 it's an allograft, it would be cadaver fascia or  9 cadaver -- usually it's cadaver fascia.  10 Q. And you are using cadaver fascia --  11 A. Now.  12 Q. -- at this time?  13 A. Now.  14 Q. Okay. So they are not saying that's --  15 that the mesh is better than cadaver or one way  16 or the other, they're just saying there is  17 insufficient evidence at this time?  18 A. Correct. And this is comparing  19 absorbable mesh, which is different than Prosima  20 or Prolift or Gynemesh.  21 Q. Okay. And then they finish with: "In  22 2011, many transvaginal permanent meshes were  23 voluntarily withdrawn from the market, and the  24 newer, lightweight transvaginal permanent meshes</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. On page 27 and 28 of your report.  2 A. Okay. Uh-huh. Prosima.  3 Q. And I think it's the very last  4 sentence, which is why I made it 27, 28.  5 "The overall anatomic success rate of  6 Prolift and Prolift+M was evaluated by Sikirica  7 in 2008."  8 Do you see that?  9 A. Uh-huh.  10 Q. Okay. Now, there is just a listing for  11 Sikirica 2008 in your expert report --  12 A. Uh-huh.  13 Q. -- correct?  14 But in your general and supplemental  15 reliance list, you refer to a Sikirica, V., et  16 al, "Treatment Outcomes of the Gynecare Prolift  17 Pelvic Floor Repair System: A Systematic  18 Literature Review."  19 Did I read that correctly?  20 A. I'm not sure where you are.  21 Q. I was reading from your general and --  22 reliance list. Because --  23 A. Oh.  24 Q. -- your expert report just says</p>

<p style="text-align: right;">Page 273</p> <p>1 Sikirica 2008.</p> <p>2 A. That should be here. Sorry.</p> <p>3 What this is, is responsiveness of</p> <p>4 the PD and PF q months following vaginal</p> <p>5 prolapse repair augmented by mesh and vaginal</p> <p>6 support device. That's Prosima information.</p> <p>7 MR. WALKER:</p> <p>8 That may be a typographical.</p> <p>9 MR. RESTAINO:</p> <p>10 Okay. Yeah, because I'm a little</p> <p>11 confused now. Where am I getting Sikirica</p> <p>12 "Treatment Outcomes of the Gynecare Prolift</p> <p>13 Pelvic Floor Repair System"?</p> <p>14 MR. WALKER:</p> <p>15 We have the exhibits from yesterday,</p> <p>16 I'm sure. Let me grab the reliance list.</p> <p>17 A. I didn't put this together.</p> <p>18 MR. RESTAINO:</p> <p>19 Q. I understand. This happens all the</p> <p>20 time.</p> <p>21 MR. WALKER:</p> <p>22 It may not be a typo, you're right.</p> <p>23 They may have put the wrong study in when the</p> <p>24 paralegals compiled this binder of your articles.</p>	<p style="text-align: right;">Page 275</p> <p>1 Sikirica, Zyczynski.</p> <p>2 MR. WALKER:</p> <p>3 May I see?</p> <p>4 MR. RESTAINO:</p> <p>5 Yes. You can have that.</p> <p>6 MR. RESTAINO:</p> <p>7 Q. So I pulled up --</p> <p>8 A. This is what they put in -- excuse me.</p> <p>9 I'm sorry.</p> <p>10 Q. Okay.</p> <p>11 MR. WALKER:</p> <p>12 Yeah, but that's not --</p> <p>13 A. No, no. That's not related to this.</p> <p>14 They put the wrong one in.</p> <p>15 MR. RESTAINO:</p> <p>16 Q. Okay. So in your report, when you are</p> <p>17 -- when you are giving a reference for the</p> <p>18 overall anatomic success rate of Prolift or</p> <p>19 Prolift+M, what is the reference? Do you know?</p> <p>20 A. I will be -- it's the Sikirica, but</p> <p>21 it's a different article, and I have to look at</p> <p>22 it. I don't remember the exact details.</p> <p>23 Q. Okay. And do you know if you have it?</p> <p>24 A. I don't know if I have it in front of</p>
<p style="text-align: right;">Page 274</p> <p>1 A. Right.</p> <p>2 Yeah, what they put in here is a</p> <p>3 Sikirica that's associated with Prosima.</p> <p>4 MR. WALKER:</p> <p>5 They would have pulled the wrong one,</p> <p>6 then.</p> <p>7 A. Yeah.</p> <p>8 MR. WALKER:</p> <p>9 Yeah.</p> <p>10 MR. RESTAINO: .</p> <p>11 Q. Well --</p> <p>12 A. And I'm not going to have another one</p> <p>13 in here? Is the other one in here?</p> <p>14 MR. WALKER:</p> <p>15 No, they just put the wrong one in</p> <p>16 there. So we will pull it off of the --</p> <p>17 MR. RESTAINO:</p> <p>18 Q. Let me -- for what you are referring to</p> <p>19 or referencing, Sikirica --</p> <p>20 A. Uh-huh.</p> <p>21 Q. -- Sikirica 2008, is this it here? And</p> <p>22 I apologize for not being able to blow that up.</p> <p>23 Is that your reference?</p> <p>24 A. No. This is a -- it's -- no, this is a</p>	<p style="text-align: right;">Page 276</p> <p>1 me.</p> <p>2 Q. Okay.</p> <p>3 A. I have seen it.</p> <p>4 Q. Let me just ask some --</p> <p>5 MR. WALKER:</p> <p>6 He's not going to have it if it's not</p> <p>7 in his binder.</p> <p>8 MR. RESTAINO:</p> <p>9 Q. What I have pulled and what you just</p> <p>10 showed me were two abstracts. Do you know if</p> <p>11 what you are referring to was an abstract or an</p> <p>12 actual journal article?</p> <p>13 A. I think it was an abstract.</p> <p>14 Q. Okay. Okay. Now, just talking about</p> <p>15 abstracts for a moment, they are not a full</p> <p>16 article with all the data; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And they are not published like an</p> <p>19 article in a medical journal?</p> <p>20 A. Not that I'm aware of.</p> <p>21 Q. And they are not peer-reviewed?</p> <p>22 A. I'm not -- I'm not sure. I don't think</p> <p>23 they are.</p> <p>24 Q. Okay.</p>



<p style="text-align: right;">Page 277</p> <p>1 A. But I'm not sure.</p> <p>2 Q. Next is -- in your expert report, on</p> <p>3 page 28, paragraph c --</p> <p>4 A. Uh-huh.</p> <p>5 Q. -- you then write: "In 2011, Dr.</p> <p>6 Alfredo Milani and colleagues" --</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. " -- including Dr. Piet Hinoul, Judi</p> <p>10 Gauld, and Vanja Sikirica from Ethicon -</p> <p>11 published the results of a prospective</p> <p>12 multi-center cohort study involving 127 patients</p> <p>13 treated with Prolift+M."</p> <p>14 Why did you add that these three</p> <p>15 individuals were from Ethicon, if you recall?</p> <p>16 A. Because it was part of the study.</p> <p>17 Q. Okay. So the study itself is titled</p> <p>18 "Trocac-guided Mesh Repair of Vaginal Prolapse</p> <p>19 Using Partially Absorbable Mesh: 1 Year</p> <p>20 Outcomes"; correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. Good. We're on the same page.</p> <p>23 All right. I'll go ahead and then have</p> <p>24 this marked as 31, I believe.</p>	<p style="text-align: right;">Page 279</p> <p>1 A. Yes.</p> <p>2 Q. So at the 3-month period and the 1-year</p> <p>3 follow-up period, are both below the 24 minimum,</p> <p>4 and that was espoused by Benbouzid,</p> <p>5 B-E-N-B-O-U-Z-I-D, and the published expert</p> <p>6 opinions of Barber, et al.; correct?</p> <p>7 A. Less than 24 months, yes.</p> <p>8 Q. If you can turn to 28 and paragraph d</p> <p>9 of your expert report.</p> <p>10 A. Uh-huh. D, uh-huh.</p> <p>11 Q. And again there is another paper by</p> <p>12 Milani, M-I-L-A-N-I; correct?</p> <p>13 A. Uh-huh.</p> <p>14 Q. This one's titled "Medium-Term Clinical</p> <p>15 Outcomes Following Trocar-Guided Mesh Repair of</p> <p>16 Vaginal Prolapse Using Partially Absorbable</p> <p>17 Mesh"?</p> <p>18 A. Right.</p> <p>19 Q. This is published in the International</p> <p>20 Urogynecological Journal; correct?</p> <p>21 A. Correct.</p> <p>22 Q. What color is that?</p> <p>23 A. I don't know. Oh, sorry. It doesn't</p> <p>24 have a color. I was just going to say that.</p>
<p style="text-align: right;">Page 278</p> <p>1 (Defendant's Exhibit Number 31 was</p> <p>2 marked for identification.)</p> <p>3 A. This is from the gray journal, American</p> <p>4 Journal of OB/GYN. We call it the gray journal.</p> <p>5 It's the same thing.</p> <p>6 MR. RESTAINO:</p> <p>7 Q. And you said that yesterday and I</p> <p>8 forgot to ask you, why is it called the gray</p> <p>9 journal?</p> <p>10 A. Because it's gray. And there is a</p> <p>11 green journal. Which the ACOG is green. Yeah,</p> <p>12 very scientific how we came up with that.</p> <p>13 MR. WALKER:</p> <p>14 You ask a question, you get an answer.</p> <p>15 MR. RESTAINO:</p> <p>16 Q. Okay. So in the abstract of this</p> <p>17 Milani article, the study design is a prospective</p> <p>18 multicentre cohort study at 11 international</p> <p>19 sites.</p> <p>20 A. Uh-huh.</p> <p>21 Q. 127 patients with pelvic organ prolapse</p> <p>22 stage greater than or equal to III had surgery</p> <p>23 and were evaluated at 3 months and 1 year</p> <p>24 postsurgery compared with baseline; correct?</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. Okay. Now, I'm marking this Milani</p> <p>2 reference as 32.</p> <p>3 (Defendant's Exhibit Number 32 was</p> <p>4 marked for identification.)</p> <p>5 MR. RESTAINO:</p> <p>6 Q. This is another abstract; correct?</p> <p>7 A. Correct. This is a follow-up on this</p> <p>8 report.</p> <p>9 Q. Okay.</p> <p>10 A. Got you.</p> <p>11 Q. And as an abstract, it doesn't contain</p> <p>12 all the study data; correct?</p> <p>13 Let me strike that and let me ask it</p> <p>14 differently.</p> <p>15 A. Yeah.</p> <p>16 Q. As you probably are aware from</p> <p>17 reviewing the literature, most, if not all,</p> <p>18 studies in the discussion aspect of it -- and I</p> <p>19 believe yesterday you stated you start off by</p> <p>20 reading conclusions and discussion and then go</p> <p>21 through their tables, et al.</p> <p>22 A. Correct.</p> <p>23 Q. Many times the studies will list the</p> <p>24 strengths and the weaknesses or limitations of</p>

<p style="text-align: right;">Page 281</p> <p>1 the study; --</p> <p>2 A. Right.</p> <p>3 Q. -- correct?</p> <p>4 A. Correct.</p> <p>5 Q. In an abstract, there is not enough</p> <p>6 room to do that. So in this abstract, they don't</p> <p>7 list any weaknesses or limitations of their</p> <p>8 study, do they?</p> <p>9 A. Correct.</p> <p>10 Q. And as we previously discussed, the</p> <p>11 abstracts do not go through the same peer-review</p> <p>12 as a published article; correct?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. So, now on page 29 e, 29 of your</p> <p>15 expert report, paragraph e, you talk about</p> <p>16 Bhatia, B-H-A-T-I-A, writing: "Bhatia and</p> <p>17 colleagues reported on the results of a</p> <p>18 retrospective cohort study measuring sexual</p> <p>19 health following surgery with Prolift and</p> <p>20 Prolift+M."</p> <p>21 MR. WALKER:</p> <p>22 You're into Prosima now.</p> <p>23 MR. RESTAINO:</p> <p>24 Yeah.</p>	<p style="text-align: right;">Page 283</p> <p>1 A. Yes.</p> <p>2 Q. And do you have that study?</p> <p>3 A. Yep.</p> <p>4 Q. And -- well, let me ask you, because it</p> <p>5 might be from your expert report, but this is a</p> <p>6 13-month follow-up study --</p> <p>7 A. Correct.</p> <p>8 Q. -- correct?</p> <p>9 A. Yes.</p> <p>10 Q. And so, once again, it would be less</p> <p>11 than the 24 months espoused by Benbouzid and</p> <p>12 Barber's expert opinion; correct?</p> <p>13 A. It's not 24 months.</p> <p>14 Q. Okay. And then they report a mesh</p> <p>15 exposure rate, and you put in your expert report,</p> <p>16 of 2.2 percent. Is that correct?</p> <p>17 A. Uh-huh.</p> <p>18 Q. Now, the 2.2 percent is well below that</p> <p>19 that was even reported by the Cochrane group that</p> <p>20 we were discussing yesterday --</p> <p>21 A. Right.</p> <p>22 Q. -- correct?</p> <p>23 A. Yes.</p> <p>24 Q. Now, we had a discussion, and defense</p>
<p style="text-align: right;">Page 282</p> <p>1 Q. The -- the reference is Comparison of</p> <p>2 Sexual Function Outcomes 1 Year After Undergoing</p> <p>3 a Transvaginal Mesh Procedure Using Polypropylene</p> <p>4 Mesh Versus Hybrid Polypropylene/Poligle -- it's</p> <p>5 P-O-L-I-G-L-E-C-A-P-R-O-N-E Mesh.</p> <p>6 Did I read that correctly?</p> <p>7 A. You read that correctly, and that is</p> <p>8 +M.</p> <p>9 Q. That is +M?</p> <p>10 A. Correct.</p> <p>11 Q. And at the end of that reference, it</p> <p>12 says Oral Poster 19; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Which indicates that this is an</p> <p>15 abstract that was an oral poster at a meeting?</p> <p>16 A. Exactly.</p> <p>17 Q. So it's not a peer-reviewed published</p> <p>18 study; correct?</p> <p>19 A. That is correct.</p> <p>20 Q. Then on 29 f of your expert report, you</p> <p>21 write: "In 2013, Dr. Salil Khandwala reported on</p> <p>22 his prospective cohort study of patients treated</p> <p>23 with Prolift+M."</p> <p>24 Correct?</p>	<p style="text-align: right;">Page 284</p> <p>1 counsel also asked you, about outliers, and you</p> <p>2 indicated that you don't always include the</p> <p>3 outliers, whether low or above. Would you</p> <p>4 consider this 2.2 percent mesh exposure rate to</p> <p>5 be a low-ended outlier?</p> <p>6 A. It would be low. I'm not sure it's an</p> <p>7 outlier. It's a pretty good study. But it is</p> <p>8 low. I think that mesh -- kind of the overall</p> <p>9 mesh exposure rate is about 5 to 6 percent in</p> <p>10 most everything. So 16 percent is high. Zero is</p> <p>11 low. 2 percent is probably -- there's some other</p> <p>12 data -- there's some other ones that may say</p> <p>13 2 percent, 2 to 3 percent.</p> <p>14 Q. Okay. Thank you.</p> <p>15 Now, on page 30 of your expert report,</p> <p>16 paragraph g, you write: "Dr. Julie Quemener and</p> <p>17 colleagues reported on the results of their</p> <p>18 twenty-month follow-up study of Profit+M use in</p> <p>19 250 patients in 2014 in the European Journal of</p> <p>20 Obstetrics &amp; Gynecology and Reproductive</p> <p>21 Biology."</p> <p>22 Correct?</p> <p>23 A. Correct.</p> <p>24 Q. And if you would turn, if you have that</p>



<p style="text-align: right;">Page 285</p> <p>1 study --</p> <p>2 A. Uh-huh.</p> <p>3 Q. -- to page 196.</p> <p>4 A. 196. Yeah. Got it.</p> <p>5 Q. This is first a -- at page 196, on the</p> <p>6 top right column --</p> <p>7 A. Uh-huh.</p> <p>8 Q. -- do you see where they write "in our</p> <p>9 study, comma"?</p> <p>10 A. Yes.</p> <p>11 Q. "The global rate of reinterventions</p> <p>12 after transvaginal Prolift+M mesh repair was</p> <p>13 around 8 percent with a median follow-up of</p> <p>14 20 months. The rate of reinterventions for</p> <p>15 recurrent prolapse was only 1.2 percent after</p> <p>16 Prolift+M in our series but we must underline it,</p> <p>17 is certainly underestimated as follow-up was</p> <p>18 relatively short."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes, you did.</p> <p>21 Q. And so she is, in essence, agreeing</p> <p>22 with Benbouzid and Barber, et al., that at least</p> <p>23 here, without her saying 24 months, she's saying</p> <p>24 that 20 months is a relatively short follow-up</p>	<p style="text-align: right;">Page 287</p> <p>1 A. No problem.</p> <p>2 Q. Okay. Now, Prosima is also removed</p> <p>3 from the market; correct?</p> <p>4 A. Correct.</p> <p>5 Q. On page 31, paragraph b --</p> <p>6 A. Yep.</p> <p>7 Q. -- you write: "Like Prolift, it</p> <p>8 underwent many years of study with development</p> <p>9 and testing of surgical technique, prototype, and</p> <p>10 mesh configuration. Studies began in 2004, and</p> <p>11 the device was not introduced until more than</p> <p>12 five years later."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. Now, is it your understanding that</p> <p>16 Prosima, like Prolift and Gynemesh PS, went</p> <p>17 through the 510(k) approval process?</p> <p>18 MR. WALKER:</p> <p>19 I object to the form.</p> <p>20 A. I'm not sure. We talked about this</p> <p>21 yesterday a little bit. I believe -- I don't</p> <p>22 know what -- you talked about predicate before.</p> <p>23 I think this went through the 510(k), yes.</p> <p>24 MR. RESTAINO:</p>
<p style="text-align: right;">Page 286</p> <p>1 period --</p> <p>2 A. Right.</p> <p>3 MR. WALKER:</p> <p>4 Object to the form.</p> <p>5 MR. RESTAINO:</p> <p>6 Q. -- correct?</p> <p>7 Now, as we discussed yesterday, she</p> <p>8 says a median follow-up. So the median means</p> <p>9 half is less and half is more?</p> <p>10 A. Uh-huh.</p> <p>11 Q. So in this one study, half the studies</p> <p>12 -- or half the follow-up was less than</p> <p>13 20 months --</p> <p>14 A. Right.</p> <p>15 Q. -- correct?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. Now we are moving on to Prosima.</p> <p>18 A. Okay.</p> <p>19 Q. And if you would turn to page 30 of</p> <p>20 your expert report.</p> <p>21 A. Yes.</p> <p>22 Q. And I apologize. I don't know if it</p> <p>23 needs to be said, but as per yesterday, if you</p> <p>24 need to take a break at any time, call time out.</p>	<p style="text-align: right;">Page 288</p> <p>1 Q. So if it's approved based upon a</p> <p>2 predicate, then it doesn't have to go through</p> <p>3 preclinical, phase 1, phase 2, phase 3, clinical</p> <p>4 trials; correct?</p> <p>5 A. Correct.</p> <p>6 MR. WALKER:</p> <p>7 Object to the form.</p> <p>8 MR. RESTAINO:</p> <p>9 Q. So I was a little confused, then. When</p> <p>10 you write, "Studies began in 2004, and the device</p> <p>11 was not introduced until more than five years</p> <p>12 later," what studies are you referring to?</p> <p>13 Because they're not referenced.</p> <p>14 A. I think they were doing internal</p> <p>15 studies and they didn't like the results, so they</p> <p>16 wanted to get more data before they put it out,</p> <p>17 which was good for the company.</p> <p>18 Q. Now, I think -- as we were discussing</p> <p>19 off the record yesterday, there is such a thing</p> <p>20 as realtime where I could read through and I</p> <p>21 could see your answer, but I think you said, I</p> <p>22 think it went through internal studies. Do you</p> <p>23 know that for sure?</p> <p>24 A. I'm almost positive. I don't know all</p>

<p style="text-align: right;">Page 289</p> <p>1 the details about that. I've looked at that  2 before. I want to say it did. I want to say  3 they were doing internal studies and they didn't  4 like the data and they kept -- kept going on it  5 till they got -- till they felt like it was --  6 the data was complete.  7 Q. Without beating a dead horse, it says:  8 "Like Profit, it underwent many years of study  9 with development ..."  10 Did someone from Ethicon tell you that  11 or where are you getting that from?  12 A. I must have been told that.  13 Q. Okay. On page 31 of your expert  14 report, still in paragraph b, you write: "The  15 12- and 24-month Prosima study results  16 demonstrated good efficacy and a positive safety  17 profile." Reference 75.  18 Correct?  19 A. That's Zyczynski. Yes.  20 Q. That's who?  21 A. Zyczynski.  22 Q. I was wondering how that was going to  23 be pronounced.  24 Okay. Let's go ahead and mark</p>	<p style="text-align: right;">Page 291</p> <p>1 (Defendant's Exhibit Number 33 was  2 marked for identification.)  3 MR. RESTAINO:  4 Q. Okay. How do you pronounce that name?  5 A. Zyczynski.  6 Q. Zyczynski. Okay. So Zyczynski is  7 looking at data from 12 to 24 months with  8 Prosima; correct?  9 A. Correct.  10 Q. So, as we've now discussed with three  11 papers, less than 24 months is considered  12 short-term, and as Barber said, you cannot draw  13 concrete conclusions from that data; correct?  14 A. Correct.  15 MR. WALKER:  16 I just want to make sure the record is  17 clear. I think Zyczynski is only looking at  18 12-month data. Sayer is looking at the longer  19 term data.  20 A. I think it's 29 months for Sayer, too,  21 yeah.  22 MR. WALKER:  23 The Zyczynski is just 12 months.  24 MR. RESTAINO:</p>
<p style="text-align: right;">Page 290</p> <p>1 Zyczynski.  2 MR. WALKER:  3 And Sayer. You are putting that 75  4 reference as two studies? I just want to make  5 sure.  6 A. Yeah, I think I have them both.  7 MR. WALKER:  8 They put both of them in there?  9 A. I think they did.  10 MR. RESTAINO:  11 It does, Jordan, and I have that.  12 Thank you for pointing it out.  13 MR. WALKER:  14 Zyczynski and Sayer?  15 MR. RESTAINO:  16 Right.  17 MR. WALKER:  18 I just wanted to make sure they put  19 Sayer in since it's kind of --  20 A. Since we've got --  21 MR. RESTAINO:  22 Let me see which one of these is best.  23 This one. Let's go ahead and mark the Zyczynski  24 as next.</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. Okay. So when --  2 A. One-year assessment. Excuse me.  3 One-year assessment, that's right.  4 Q. So when you write the 12- and 24-month  5 Prosima study results with reference 75, that's  6 why you have the two references?  7 A. Correct.  8 Q. Perfect. Thank you.  9 And, Jordan, thank you.  10 So with Zyczynski, if you look at the  11 article itself, this is a -- was this a  12 retrospective or prospective study?  13 A. It was a prospective, I believe. Yes.  14 Q. Okay. There is not a control group;  15 correct?  16 A. Correct.  17 Q. And there wasn't any blinding?  18 A. Correct.  19 Q. And no randomization?  20 A. Correct.  21 Q. With 12 months of follow-up?  22 A. Correct.  23 Q. Now, in looking at the Sayer study, and  24 I'm not going to mark it, but if you have it</p>

<p style="text-align: right;">Page 293</p> <p>1 available, that is the one that you are utilizing 2 and referencing for the 24-month data? 3 A. Correct. It's medium-term clinical 4 outcomes. 5 Q. Okay. Still no randomization? 6 A. No. No, there is not, and it says 7 greater than two years following surgery. 8 Q. Okay. So it is past the 2 -- 24-month 9 mark, but no randomization, no control group and 10 no blinding -- 11 A. Correct. 12 Q. -- correct? 13 A. Yes. 14 Q. Then about 10 lines down on page 31, 15 paragraph b? 16 A. This is on my report? 17 Q. Now back to your report. I apologize. 18 A. Okay. Let me get to that. 19 All right. 31. Go back. I'm sorry. 20 Where are we? 31? 21 Q. On 31 b, 10 lines down. 22 A. Okay. 23 Q. It's -- you write: "There were several 24 studies of Prosima which demonstrated its</p>	<p style="text-align: right;">Page 295</p> <p>1 Q. And there is a section there about 2 cytotoxicity -- 3 A. Uh-huh. 4 Q. -- correct? And how -- in your report, 5 how are you defining cytotoxicity? 6 A. I would say cytotoxicity would be 7 defined as breakdown of the coating of the mesh, 8 if there were any, causing problems with the 9 cells in the vagina. 10 Q. Causing problems with the cells? Okay. 11 Because -- 12 A. Yeah. For whatever reason. 13 Q. -- my definition of cytotoxicity would 14 be death of cells from something. 15 A. Okay. Okay. 16 Q. And I want to make sure we are using -- 17 on the same -- using -- 18 A. What I'm thinking is that that's what 19 the alleged problem is, that this breakdown of 20 the coating and whatever causes the cells to die, 21 the cytotoxicity of the cells. 22 Q. Okay. Okay. 23 A. And I don't agree with that. 24 Q. Okay. Would you agree that with deaths</p>
<p style="text-align: right;">Page 294</p> <p>1 efficacy and safety." 2 Do you see that? 3 A. Yes. 4 Q. But there's no references there; 5 correct? 6 A. Correct. 7 Q. Can you tell me what studies you were 8 relying upon there? 9 A. There were just lots of ones I read, 10 and so I didn't document -- I mean, I didn't 11 document that. 12 Q. Okay. 13 Let's go off the record for one moment. 14 Okay? 15 (Off the record.) 16 MR. RESTAINO: 17 Q. Okay. So we are going to go to the 18 section of your expert report now right around 31 19 or so -- I didn't write it down -- where you talk 20 about design defects. 21 MR. WALKER: 22 That's 37. 23 A. Okay. Got it. 24 MR. RESTAINO:</p>	<p style="text-align: right;">Page 296</p> <p>1 -- with death of cells from any agent, including 2 bacteria, that -- well, let's use bacteria. When 3 bacteria gets in the body and our body's 4 responding, the immune system is going to respond 5 with white blood cells, macrophages and all those 6 other critters that come crawling down in battle; 7 correct? 8 A. Correct. 9 Q. And in this battle, there's death of 10 bacteria, but also death of the good guys, and 11 the result of all that is pus; agreed? 12 A. Yes. 13 Q. Okay. And would you agree that when 14 any foreign body gets into the body, that there 15 is some degree of a foreign body reaction? 16 A. Yes. 17 Q. When they transplant livers, for 18 example, they have to give medication to decrease 19 the immune system; correct? 20 A. Correct. 21 Q. And with any foreign body that's 22 implanted, a biofilm will be formed around it by 23 the body? 24 A. It can.</p>

<p style="text-align: right;">Page 297</p> <p>1 Q. Correct?</p> <p>2 A. That's true.</p> <p>3 Q. Okay. Now, when a foreign body such as</p> <p>4 a knee implant, artificial heart, finger and toe</p> <p>5 implants, are put in, those foreign bodies do not</p> <p>6 have an inherent blood supply; would you agree?</p> <p>7 A. Right.</p> <p>8 Q. So, therefore, if a -- if an implant of</p> <p>9 any sort becomes embedded with bacteria,</p> <p>10 contaminated, even infected, it's more difficult</p> <p>11 to treat because the immune system cells can't</p> <p>12 get to it, antibiotics can't really get to it,</p> <p>13 which is why many times infected knee implants</p> <p>14 have to be taken out; correct?</p> <p>15 A. You are talking about knee implants,</p> <p>16 not mesh necessarily?</p> <p>17 Q. Right now I'm talking about other</p> <p>18 implants.</p> <p>19 A. Got you. Yes, I agree.</p> <p>20 Q. Which is why, for example, individuals</p> <p>21 with artificial heart valves, when they go in for</p> <p>22 teeth cleaning, they have to be given</p> <p>23 prophylactics, antibiotics, to hopefully prevent</p> <p>24 it from becoming infected?</p>	<p style="text-align: right;">Page 299</p> <p>1 if I have it. Ah. Yes. I have this.</p> <p>2 (Defendant's Exhibit Number 34 was</p> <p>3 marked for identification.)</p> <p>4 MR. RESTAINO:</p> <p>5 Q. If you go to the last two sentences, I</p> <p>6 believe it's the first paragraph, left column.</p> <p>7 And he talks about chronic infections. Did I</p> <p>8 list that correctly?</p> <p>9 A. No. Down on the first page --</p> <p>10 Q. Yeah. You know, I didn't put the page</p> <p>11 number. I'm sorry. Let me bring it up real</p> <p>12 quick and I will find it. I apologize.</p> <p>13 A. No problem.</p> <p>14 Q. Okay. First of all, this -- the title</p> <p>15 of this story -- of this article is "Basic</p> <p>16 Science and Clinical Aspects of Mesh Infection in</p> <p>17 Pelvic Floor Reconstructive Surgery"; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And this is, again, in the</p> <p>20 International Urogynecological Journal (2011),</p> <p>21 the uncolored journal?</p> <p>22 A. Uncolored.</p> <p>23 Q. Okay.</p> <p>24 A. Rainbow.</p>
<p style="text-align: right;">Page 298</p> <p>1 A. That's true.</p> <p>2 Q. Does not the same risk apply to mesh in</p> <p>3 the pelvis and/or vagina?</p> <p>4 A. The difference with the mesh is that</p> <p>5 the mesh has pores in it so that the blood</p> <p>6 vessels can get -- the blood vessels and the</p> <p>7 macro -- macrophages and the fibrin can deposit</p> <p>8 and it can support it, so it becomes part of the</p> <p>9 tissue. The way I look at it, it becomes part of</p> <p>10 the tissue. It's different than a -- just an</p> <p>11 inert piece that has no -- that is -- especially</p> <p>12 because of the large pores. An inert piece of</p> <p>13 tissue or of a foreign body, if you will, that</p> <p>14 doesn't get incorporated with the tissue. The</p> <p>15 tissue is the ticket with making mesh different</p> <p>16 than any other implant.</p> <p>17 Q. Okay. Are you saying, then, that the</p> <p>18 risk of long-term infection with mesh doesn't</p> <p>19 exist or is decreased?</p> <p>20 A. It's minimal.</p> <p>21 Q. Okay. Now, I want to mark as next a</p> <p>22 paper I believe you reference. The last name is</p> <p>23 d-e, and then capital T a-y-r-a-c?</p> <p>24 A. Yes, that name's familiar. Let me see</p>	<p style="text-align: right;">Page 300</p> <p>1 Q. So if you'd turn to page 776. My</p> <p>2 apologies.</p> <p>3 A. Yes. Got it.</p> <p>4 Q. Okay. The first full paragraph on the</p> <p>5 left. The paragraph starts "In other words."</p> <p>6 A. Uh-huh.</p> <p>7 Q. Okay. If you look down towards the</p> <p>8 bottom, it's one, two, three, four sentences --</p> <p>9 four lines up. He writes "chronic infections."</p> <p>10 A. Yes.</p> <p>11 Q. Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. "Chronic infections may therefore</p> <p>14 appear several months or even several years after</p> <p>15 mesh implantation. The mechanism of chronic</p> <p>16 infection may also explain the low bacterial</p> <p>17 density usually found on explanted meshes."</p> <p>18 Did I read that correct -- correctly?</p> <p>19 A. Yes, you did.</p> <p>20 Q. And for the record, could you define</p> <p>21 what is meant by an explanted mesh?</p> <p>22 A. When a mesh is removed for whatever</p> <p>23 reason. They were doing biologic studies -- I</p> <p>24 mean they were doing cultures of it and they had</p>

<p style="text-align: right;">Page 301</p> <p>1 low bacteria.</p> <p>2 Q. Okay. You mentioned yesterday, correct</p> <p>3 me if I'm wrong, that you have removed pieces of</p> <p>4 mesh but never a full mesh?</p> <p>5 A. Never had to remove all the mesh.</p> <p>6 Q. Okay. When you've removed the pieces</p> <p>7 of mesh, have you sent that to the laboratory for</p> <p>8 culture?</p> <p>9 A. I have not.</p> <p>10 Q. So you don't know the bacteria count in</p> <p>11 those?</p> <p>12 A. I do not know my personal count, but I</p> <p>13 will say, I have never seen mesh that --</p> <p>14 explanted that had pus around it.</p> <p>15 Q. Or what some people would call --</p> <p>16 A. Infection.</p> <p>17 Q. -- a frank infection?</p> <p>18 A. Correct.</p> <p>19 Q. Okay. If we return now again to your</p> <p>20 expert report, page 37, VI, paragraph A.</p> <p>21 A. All right. Now, tell me again where I</p> <p>22 am.</p> <p>23 MR. WALKER:</p> <p>24 Page 30 -- no. Page 37?</p>	<p style="text-align: right;">Page 303</p> <p>1 Q. Did you -- have you ever read his</p> <p>2 depositions in the litigation?</p> <p>3 A. I have not read his depositions.</p> <p>4 Q. I'm going to ask the court reporter to</p> <p>5 mark as the next -- I think --</p> <p>6 Where are we, 35, Jordan?</p> <p>7 Article by Klinge, et al. "Foreign</p> <p>8 Body Reaction to Meshes Used for the Repair of</p> <p>9 Abdominal Wall Hernias."</p> <p>10 A. I got you.</p> <p>11 MR. WALKER:</p> <p>12 Thank you.</p> <p>13 MR. RESTAINO:</p> <p>14 You're welcome.</p> <p>15 MR. WALKER:</p> <p>16 This is exhibit what?</p> <p>17 MR. RESTAINO:</p> <p>18 35?</p> <p>19 THE COURT REPORTER:</p> <p>20 35.</p> <p>21 MR. WALKER:</p> <p>22 So the de Tayrac is 34?</p> <p>23 THE COURT REPORTER:</p> <p>24 Yes.</p>
<p style="text-align: right;">Page 302</p> <p>1 MR. RESTAINO:</p> <p>2 Q. Page 37, VI, paragraph A.</p> <p>3 A. Okay. Yeah, yeah, yeah. Sorry.</p> <p>4 Q. "The clinical data demonstrates that</p> <p>5 the knitted, monofilament, lightweight,</p> <p>6 macroporous Prolene polypropylene mesh is</p> <p>7 biocompatible, has a minimal inflammatory</p> <p>8 response, and allows for adequate tissue growth,</p> <p>9 the mechanism by which mesh ultimately provides</p> <p>10 the necessary structural support in women with</p> <p>11 pelvic organ prolapse."</p> <p>12 Did I read that correctly?</p> <p>13 A. Yes.</p> <p>14 Q. Now, the mesh, as we discussed</p> <p>15 yesterday, in all of these mesh devices is the</p> <p>16 Prolene polypropylene mesh which got its start in</p> <p>17 the hernia surgery; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And I believe you -- you mentioned or</p> <p>20 referenced at one point a Dr. Klinge,</p> <p>21 K-L-I-N-G-E?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know who he is?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 304</p> <p>1 MR. RESTAINO:</p> <p>2 Yes.</p> <p>3 (Defendant's Exhibit Number 35 was</p> <p>4 marked for identification.)</p> <p>5 A. And this was 1999.</p> <p>6 MR. RESTAINO:</p> <p>7 Q. Correct.</p> <p>8 A. Got you.</p> <p>9 Q. So this was before you were even using</p> <p>10 mesh --</p> <p>11 A. Correct.</p> <p>12 Q. -- down in the pelvis; correct?</p> <p>13 A. Yes.</p> <p>14 Q. If you look at the abstract, you see</p> <p>15 the objective is to investigate the local tissue</p> <p>16 reactions to meshes that have been removed from</p> <p>17 humans; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And under material: "Samples of 17</p> <p>20 nonabsorbable meshes (1 polyester, 10</p> <p>21 polypropylene, 2 reduced polypropylene, and 4</p> <p>22 polytetrafluorethylene, PTFE) and 1 absorbable</p> <p>23 mesh (polyglactin 910) that had been implanted</p> <p>24 for repair of abdominal wall defects."</p>



<p style="text-align: right;">Page 305</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. So of these studies -- or of these 17</p> <p>4 meshes, 10 of them are the polypropylene which we</p> <p>5 are discussing?</p> <p>6 A. Correct.</p> <p>7 Q. Or Prolene?</p> <p>8 And then under interventions, he used</p> <p>9 light and transmission electron microscopy,</p> <p>10 immunohistochemistry, and histological</p> <p>11 examination; correct?</p> <p>12 A. Yes.</p> <p>13 Q. Now, under results, he writes: "Light</p> <p>14 microscopy showed chronic inflammatory tissue</p> <p>15 reaction, even after years, with pronounced</p> <p>16 differences among materials. Partial volume of</p> <p>17 inflammatory cells (percentage) varied from 32 in</p> <p>18 polypropylene, to 12 in expanded PTFE, 8 in</p> <p>19 polyester, and 7 in reduced polypropylene."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes, you did.</p> <p>22 Q. So when he's quantifying the volume of</p> <p>23 inflammatory cells, the greatest percentage was</p> <p>24 seen with polypropylene in this study?</p>	<p style="text-align: right;">Page 307</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. Now, the inflammation of a foreign body</p> <p>4 many times, for some of the lay people, that's</p> <p>5 the identical inflammation that someone may have</p> <p>6 at the bottom of their foot if they get a</p> <p>7 splinter at the boardwalk; correct?</p> <p>8 A. Yes.</p> <p>9 Q. And that's painful or can be painful?</p> <p>10 A. An acute infection can be painful, yes.</p> <p>11 Q. And have you ever had a patient that</p> <p>12 was spitting a suture?</p> <p>13 A. Yes.</p> <p>14 Q. So you're familiar with that term?</p> <p>15 A. Yes, uh-huh.</p> <p>16 Q. Can you describe that term probably</p> <p>17 better than I can?</p> <p>18 A. Well, where I've had patients spit</p> <p>19 sutures are when we used to use -- do uterosacral</p> <p>20 suspensions, and we use permanent sutures there,</p> <p>21 and sometimes the suture would come out through</p> <p>22 the top of the cuff.</p> <p>23 Q. And is the spitting of the suture a</p> <p>24 response by the body trying to get rid of this</p>
<p style="text-align: right;">Page 306</p> <p>1 A. Yes, in this study.</p> <p>2 Q. Then he writes: "In meshes implanted</p> <p>3 for long periods there were still numerous</p> <p>4 macrophages at the interface between tissue and</p> <p>5 polypropylene (45 percent), polyester</p> <p>6 (45 percent), expanded PTFE (25 percent), and</p> <p>7 reduced polypropylene (22 percent)."</p> <p>8 And did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. And as we were discussing a little</p> <p>11 while ago, macrophages are part of the body's</p> <p>12 innate immune system that responds to infections</p> <p>13 or foreign bodies --</p> <p>14 A. Correct.</p> <p>15 Q. -- correct?</p> <p>16 A. Yes.</p> <p>17 Q. "Conclusion: Inflammation around</p> <p>18 alloplastic materials used to repair defects in</p> <p>19 the abdominal wall persists for many years.</p> <p>20 There was evidence of long-term wound</p> <p>21 complications as a result of persistent foreign</p> <p>22 body reaction. Further studies are required to</p> <p>23 evaluate the long-term tissue response to these</p> <p>24 materials."</p>	<p style="text-align: right;">Page 308</p> <p>1 foreign body?</p> <p>2 A. Yes.</p> <p>3 Q. And have patients complained of the</p> <p>4 pain of that?</p> <p>5 A. They really didn't complain of pain.</p> <p>6 In the situation of the vagina, it's more they</p> <p>7 don't -- it doesn't hurt. It's more of a --</p> <p>8 usually they have a discharge or a little pink</p> <p>9 discharge or something like that.</p> <p>10 Q. Have you had patients complain of</p> <p>11 painful embedded sutures, for example, with -- in</p> <p>12 skin incisions?</p> <p>13 A. Yes. Yes.</p> <p>14 Q. When you are using stitches, whether</p> <p>15 it's in the pelvis, vagina or skin -- let's use</p> <p>16 simple sutures that are running, for example, for</p> <p>17 a moment. You tie your knot and then either</p> <p>18 yourself, your assistant or the nurse cuts the</p> <p>19 knot; correct?</p> <p>20 A. Correct. Uh-huh.</p> <p>21 Q. Leaving two little tiny antennae?</p> <p>22 A. Correct.</p> <p>23 Q. This is one of those estimate</p> <p>24 questions.</p>



<p style="text-align: right;">Page 309</p> <p>1 A. Sure.</p> <p>2 Q. If you were to take that stitch out,</p> <p>3 with tiny forceps very carefully untie it --</p> <p>4 A. Okay.</p> <p>5 Q. -- can you estimate the length of that</p> <p>6 stitch?</p> <p>7 A. You could.</p> <p>8 Q. And what would you say, how long was a</p> <p>9 typical stitch?</p> <p>10 A. 2 millimeters.</p> <p>11 Q. Okay. 2 millimeters?</p> <p>12 A. That's an estimate.</p> <p>13 Q. Sure. 2 millimeters.</p> <p>14 With -- let's talk about the mesh first</p> <p>15 for prolapse.</p> <p>16 A. Uh-huh.</p> <p>17 Q. Has anyone from Ethicon ever told you</p> <p>18 how much mesh is -- how much polypropylene is in</p> <p>19 that mesh?</p> <p>20 A. I'm not sure.</p> <p>21 MR. WALKER:</p> <p>22 Object to the form.</p> <p>23 A. I'm not sure. Restate that.</p> <p>24 MR. RESTAINO:</p>	<p style="text-align: right;">Page 311</p> <p>1 that he's talking about, the pore sites aren't as</p> <p>2 big. I think that changes a little bit with pore</p> <p>3 size. The fact that -- the way it's -- the</p> <p>4 macrophages respond and all, I think it's less</p> <p>5 reactive than in the 1999 study, in the pore size</p> <p>6 that was used in the mesh he was talking about.</p> <p>7 MR. RESTAINO:</p> <p>8 Q. I think yesterday you shared with us</p> <p>9 that as the mesh was designed for use in the</p> <p>10 vagina or pelvis, the pores became larger and the</p> <p>11 mesh more flexible, is the word I think you used?</p> <p>12 A. Yeah.</p> <p>13 Q. Okay.</p> <p>14 A. Yes.</p> <p>15 Q. Now I'll go ahead and ask that the</p> <p>16 court reporter mark as Exhibit 36 an article,</p> <p>17 lead author Nolfi, N-O-L-F-I.</p> <p>18 (Defendant's Exhibit Number 36 was</p> <p>19 marked for identification.)</p> <p>20 MR. RESTAINO:</p> <p>21 Q. Have you seen this before?</p> <p>22 A. Is it -- with reference to me, this</p> <p>23 does not look familiar to me. I'm not saying I</p> <p>24 haven't seen it, but I don't recognize it.</p>
<p style="text-align: right;">Page 310</p> <p>1 Q. Has anyone ever shared with you that</p> <p>2 there are over 400 yards of stitch material --</p> <p>3 A. Oh --</p> <p>4 Q. -- in that mesh?</p> <p>5 MR. WALKER:</p> <p>6 Object to the form.</p> <p>7 A. I've never heard that.</p> <p>8 MR. RESTAINO:</p> <p>9 Q. And stating the obvious, 400 yards is a</p> <p>10 lot more than 2 millimeters; correct?</p> <p>11 A. Correct.</p> <p>12 Q. And so, therefore, if a patient is</p> <p>13 going to have a foreign body reaction to a large</p> <p>14 volume of material, you would expect that</p> <p>15 reaction to be greater than that to a</p> <p>16 2-millimeter stitch; would you agree?</p> <p>17 A. That's possible.</p> <p>18 Q. And that would be consistent with what</p> <p>19 Klinge is writing about, a reaction that he has</p> <p>20 seen years after the polypropylene has been taken</p> <p>21 out of the abdominal wall?</p> <p>22 MR. WALKER:</p> <p>23 Object to the form.</p> <p>24 A. Except that these -- that polypropylene</p>	<p style="text-align: right;">Page 312</p> <p>1 MR. WALKER:</p> <p>2 Let's check your list here. It is not</p> <p>3 on your list.</p> <p>4 A. It does have Moalli in the -- I have a</p> <p>5 Moalli paper in my list, but --</p> <p>6 MR. RESTAINO:</p> <p>7 Q. It's not coming up in your general</p> <p>8 list.</p> <p>9 MR. WALKER:</p> <p>10 It's not on your reliance list.</p> <p>11 A. Got you.</p> <p>12 MR. RESTAINO:</p> <p>13 Q. The title of this is "Host Response to</p> <p>14 Synthetic Mesh in Women with Mesh Complications."</p> <p>15 Correct?</p> <p>16 A. Yes.</p> <p>17 Q. And it's published 2016 in the American</p> <p>18 Journal of Obstetrics and Gynecology?</p> <p>19 A. Yes.</p> <p>20 Q. The gray journal?</p> <p>21 A. No -- yes.</p> <p>22 Q. No?</p> <p>23 A. That's correct. Yes. Sorry.</p> <p>24 Q. Okay. Oh, and I'm sorry. I actually</p>

<p style="text-align: right;">Page 313</p> <p>1 even wrote down it's not referenced in your  2 expert report and it's not in your general  3 reliance list and it doesn't appear to be in your  4 supplemental list either.  5 A. Correct.  6 Q. If you look at the abstract, their  7 objective for their study was: "The purpose of  8 this study was to define and compare the  9 macrophage response in patients who undergo mesh  10 excision surgery for the indication of pain  11 versus a mesh exposure."  12 A. Yes.  13 Q. As we discussed a few moments ago, the  14 macrophage is one of the cells of the innate  15 immune system that responds to infection or a  16 foreign body; correct?  17 A. Correct.  18 Q. "Study Design: Patients who were  19 scheduled to undergo a surgical excision of mesh  20 for pain or exposure at Magee-Women's Hospital  21 were offered enrollment. Twenty-seven  22 mesh-vagina complexes that were removed for the  23 primary complaint of a mesh exposure (n = 15)  24 versus pain in the absence of an exposure (n =</p>	<p style="text-align: right;">Page 315</p> <p>1 surrounded each mesh fiber in both groups, with  2 predominance of the M1 subtype."  3 Did I read that correctly?  4 A. Yes.  5 Q. As you sit here today, without having a  6 chance to -- without reviewing this beforehand  7 and preparing for it, do you remember what the M1  8 macrophage is?  9 A. No.  10 Q. Okay. Good. Neither did I.  11 Okay. However, the M1 macrophage is  12 listed as a proinflammatory macrophage. They  13 write: "A prolonged M1 response is thought to  14 result in chronic inflammation and the formation  15 of foreign body giant cells with potential for  16 ongoing tissue damage and destruction."  17 Do you see where I read that?  18 A. Yes.  19 Q. Now, can you tell us what a foreign  20 body giant cell is?  21 A. Not off the top of my head. I mean, I  22 can make a guess, but I don't know.  23 Q. Okay. They then write: "M1 and M2  24 cytokines/chemokines, MMP-9 (pro- and active) and</p>
<p style="text-align: right;">Page 314</p> <p>1 12) were compared with 30 full-thickness vaginal  2 biopsy specimens from women who underwent benign  3 gynecologic surgery without mesh."  4 Did I read that correctly?  5 A. Yes.  6 Q. So in this study, they are using the  7 full-thickness vaginal biopsy specimens from  8 women who underwent benign gynecological surgery  9 as a control group --  10 A. Correct.  11 Q. -- agreed?  12 A. Yes.  13 Q. "Results: Twenty-seven mesh-vaginal  14 tissue complexes were excised from 27 different  15 women with mesh complications: 15 incontinence  16 midurethral slings and 12 prolapse meshes."  17 So, now, the incontinence midurethral  18 slings is what we are talking about today; is  19 that correct?  20 A. Correct.  21 Q. And the prolapse meshes is what we  22 talked about yesterday and this morning?  23 A. Correct.  24 Q. "On histologic examination, macrophages</p>	<p style="text-align: right;">Page 316</p> <p>1 MMP-2 (active) were increased significantly in  2 mesh-vagina explants, as compared with vagina  3 without mesh. Mesh explants that were removed  4 for exposure had 88.4 percent higher pro-MMP-9  5 (with a P value of 0.35) than those removed for  6 pain. A positive correlation was observed  7 between the profibrotic cytokine interleukin-10  8 and the percentage of M2 cells (with r's and p  9 values) in the pain group."  10 Did I read that correctly?  11 A. Yes.  12 Q. And then they conclude: "In women with  13 complications, mesh induces a pro-inflammatory  14 response that persists years after implantation.  15 The increase in MMP-9 in mesh explants that were  16 removed for exposure indicates degradation; the  17 positive association between interleukin-10 and  18 M2 macrophages in mesh explants that are removed  19 for pain is consistent with fibrosis."  20 Did I read that correctly?  21 A. Yes.  22 Q. So, now, unlike the Klinge study, where  23 you point out that the mesh was taken from the  24 abdomen and has the smaller pores, this is</p>

<p style="text-align: right;">Page 317</p> <p>1 actually prolapse and SUI mesh; correct?</p> <p>2 A. Correct.</p> <p>3 Q. And their data is indicating that the</p> <p>4 inflammatory process, as evidenced by the MMP-9</p> <p>5 and the macrophages, persists for years in some</p> <p>6 patients?</p> <p>7 A. That's what this report says, and</p> <p>8 without being able to study it, it does look like</p> <p>9 the exposure meshes had more degradation --</p> <p>10 indicates degradation, and we don't know why that</p> <p>11 -- and to me, that's not clinically significant,</p> <p>12 that it has more degradation. I think it's</p> <p>13 because it's exposed to skin. I mean air and all</p> <p>14 the forces inside the vagina as it's exposed,</p> <p>15 versus under the skin, which is not exposed to</p> <p>16 those bacteria. So --</p> <p>17 Q. (Indicating.)</p> <p>18 A. Yeah. The point is, the vagina that's</p> <p>19 explanted -- that's exposed has different things,</p> <p>20 different forces. I mean, once it's exposed, now</p> <p>21 it's exposed to everything in the vagina and that</p> <p>22 kind of thing.</p> <p>23 Q. When you are saying "exposed," are you</p> <p>24 using that for like erosion or extrusion?</p>	<p style="text-align: right;">Page 319</p> <p>1 of what we've read so far?</p> <p>2 A. Yes, except what my point was, this</p> <p>3 says the increase in MMP-9, which I'm not</p> <p>4 familiar with, never heard that before, but it</p> <p>5 says: "In mesh explants that were removed for</p> <p>6 exposure indicates degradation."</p> <p>7 My point is, for them to make the --</p> <p>8 for them to say it was degradation in the mesh is</p> <p>9 -- I think you can't make that claim necessarily</p> <p>10 because it's been exposed to things in the vagina</p> <p>11 and that kind of thing. It's a different</p> <p>12 exposure than -- I mean, the mesh is under</p> <p>13 different exposures than mesh that's under the</p> <p>14 skin is my point.</p> <p>15 Q. The --</p> <p>16 A. I'm not sure of the clinical</p> <p>17 significance of that. Excuse me. I don't mean</p> <p>18 to interrupt you, but --</p> <p>19 Q. I understand.</p> <p>20 A. -- it does make a difference. I</p> <p>21 haven't had a chance -- this is the first time</p> <p>22 I've looked at this.</p> <p>23 Q. Of course. I understand.</p> <p>24 We've been going for about an hour.</p>
<p style="text-align: right;">Page 318</p> <p>1 A. Yeah.</p> <p>2 Q. Okay.</p> <p>3 A. It's exposed, meaning that -- you know,</p> <p>4 versus the kind for pain wasn't exposed. They</p> <p>5 just went in where there was a painful spot and</p> <p>6 took it out. That's a different -- those have</p> <p>7 different forces on it is my point.</p> <p>8 Q. Okay. With that in mind, and I</p> <p>9 appreciate what you are saying, if you look back</p> <p>10 at the study design in the abstract, they do</p> <p>11 write: "Patients who were scheduled to undergo a</p> <p>12 surgical excision of mesh for pain or exposure."</p> <p>13 A. Right.</p> <p>14 Q. So I interpret that as meaning not all</p> <p>15 of them had the mesh removed because of exposure.</p> <p>16 Some of them had it removed for pain.</p> <p>17 A. Yeah, there were 12 -- 15 for pain and</p> <p>18 12 for exposure.</p> <p>19 Q. Okay. So my interpretation of this</p> <p>20 article, but I'm not the expert, is that those</p> <p>21 that are having it removed for pain are having a</p> <p>22 large foreign body reaction as evidenced by the</p> <p>23 presence of the M1 macrophages and the matrix</p> <p>24 metalloproteinase-9. Is that your interpretation</p>	<p style="text-align: right;">Page 320</p> <p>1 Why don't we take a break?</p> <p>2 MR. WALKER:</p> <p>3 Okay.</p> <p>4 (Break.)</p> <p>5 MR. RESTAINO:</p> <p>6 Q. Page 39 of your expert report.</p> <p>7 A. Uh-huh.</p> <p>8 Q. In your second sentence, you write:</p> <p>9 "There are studies that suggest clinically</p> <p>10 significant mesh degradation occurs, but there</p> <p>11 are other studies that indicate that the surface</p> <p>12 cracking interpreted by some as being evidence of</p> <p>13 mesh degradation is actually cracking in the</p> <p>14 biofield overlying the polypropylene." And then</p> <p>15 there's a reference there, number 94, with again</p> <p>16 two listings; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And the first is O-N-G, "The Myth: In</p> <p>19 Vivo Degradation of Polypropylene Meshes."</p> <p>20 A. Uh-huh.</p> <p>21 Q. Do you see that, sir?</p> <p>22 A. Yes.</p> <p>23 Q. Now, that again is an abstract that you</p> <p>24 are listing there?</p>

<p style="text-align: right;">Page 321</p> <p>1 A. Right.</p> <p>2 Q. Did you -- in looking at the abstract,</p> <p>3 what is the IUGA?</p> <p>4 A. Inter -- IUGA is International</p> <p>5 Urogynecology Association.</p> <p>6 Q. Okay. So is it your understanding this</p> <p>7 is an abstract from that association meeting?</p> <p>8 A. I need to look at it. I assume that's</p> <p>9 what it is, yes.</p> <p>10 Q. Okay.</p> <p>11 A. I don't know that for sure, but I'm</p> <p>12 pretty sure.</p> <p>13 Q. Do you know as you sit here if the</p> <p>14 abstract was ever published?</p> <p>15 A. I do not know that.</p> <p>16 Q. I'm going to have the court reporter</p> <p>17 mark as next -- 37 -- 37, an article titled "The</p> <p>18 Myth: In Vivo Degradation of Polypropylene-Based</p> <p>19 Meshes."</p> <p>20 A. Yes.</p> <p>21 (Defendant's Exhibit Number 37 was</p> <p>22 marked for identification.)</p> <p>23 MR. RESTAINO:</p> <p>24 Q. And if you see, the lead author is now</p>	<p style="text-align: right;">Page 323</p> <p>1 A. Uh-huh.</p> <p>2 Q. So these individuals are actually</p> <p>3 involved with litigation and they get the mesh</p> <p>4 that were removed and given to them, and I</p> <p>5 believe yesterday you said sometimes that you've</p> <p>6 removed them and you've given mesh to lawyers?</p> <p>7 A. Correct.</p> <p>8 Q. Okay. On page 286, the last sentence</p> <p>9 in the left upper column, it writes: "Given the</p> <p>10 limitations of previous explant studies ..."</p> <p>11 Do you see that?</p> <p>12 A. No.</p> <p>13 Q. Page 286.</p> <p>14 A. I've got 286, and where is it?</p> <p>15 Q. Last sentence, left upper column.</p> <p>16 A. Left? That's the right upper column.</p> <p>17 Q. Is it?</p> <p>18 A. Oh, yeah, it's the right upper column.</p> <p>19 Q. Okay. I'm sorry.</p> <p>20 A. Sorry.</p> <p>21 Q. "Given the limitations of previous</p> <p>22 explant studies, the purpose of the present study</p> <p>23 was to analyze the morphology and material</p> <p>24 chemistry of explanted Prolene urogynecological</p>
<p style="text-align: right;">Page 322</p> <p>1 Thames, T-H-A-M-E-S, but O-N-G, K. L., is one of</p> <p>2 the authors; correct?</p> <p>3 A. Yes. Correct. Yes.</p> <p>4 Q. Now, prior -- before I actually get to</p> <p>5 that, in your review, you do write in your expert</p> <p>6 report that there are peer-reviewed articles</p> <p>7 published that report on in vivo degradation, but</p> <p>8 you disagree with that and you use your expert</p> <p>9 report -- well, in essence you disagree with some</p> <p>10 of those studies; correct?</p> <p>11 A. Correct. Yes.</p> <p>12 Q. Now, if you look at page 286 of the</p> <p>13 Thames actual publication --</p> <p>14 MR. WALKER:</p> <p>15 Do you have that?</p> <p>16 A. Uh-huh.</p> <p>17 MR. RESTAINO:</p> <p>18 Q. -- under materials and methods --</p> <p>19 A. Yes.</p> <p>20 Q. -- you see they looked at explanted</p> <p>21 Prolene meshes (N = 78)?</p> <p>22 A. Yes.</p> <p>23 Q. And these were obtained as part of</p> <p>24 medicolegal proceedings?</p>	<p style="text-align: right;">Page 324</p> <p>1 meshes cleaned via a novel and effective cleaning</p> <p>2 process."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes.</p> <p>5 Q. And if you check on, I guess, the first</p> <p>6 page of the study, this was published online</p> <p>7 September 6th, 2016?</p> <p>8 A. Correct.</p> <p>9 Q. Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. So that's -- we are coming up on a</p> <p>12 year?</p> <p>13 A. Right.</p> <p>14 Q. Okay. And now they're writing there</p> <p>15 that this is the first time this novel cleaning</p> <p>16 process had been published within the</p> <p>17 peer-reviewed medical literature; correct?</p> <p>18 A. Correct.</p> <p>19 Q. Therefore, if anyone is attempting to</p> <p>20 replicate the study of this novel cleaning</p> <p>21 process, they haven't even had time to do that</p> <p>22 and publish it at this point?</p> <p>23 MR. WALKER:</p> <p>24 Object to the form.</p>

<p style="text-align: right;">Page 325</p> <p>1 A. As far as I can tell from this, yes.</p> <p>2 MR. RESTAINO:</p> <p>3 Q. Do you recall several years ago -- I</p> <p>4 think we are old enough to remember when there</p> <p>5 was the report of -- cold fusion had been</p> <p>6 reported?</p> <p>7 A. Yes.</p> <p>8 Q. And then all the replication studies</p> <p>9 failed to replicate it.</p> <p>10 A. Got you.</p> <p>11 Q. This study has not been replicated as</p> <p>12 of yet, to the best of your knowledge --</p> <p>13 A. Correct.</p> <p>14 Q. -- correct?</p> <p>15 A. Yes.</p> <p>16 MR. WALKER:</p> <p>17 I object to the form.</p> <p>18 MR. RESTAINO:</p> <p>19 Q. So relying upon, as your expert report</p> <p>20 does, the abstract of this, the novel cleaning</p> <p>21 process that they report upon has not been</p> <p>22 reported on by anybody else?</p> <p>23 A. Not that I'm aware of.</p> <p>24 Q. Okay. So as you sit here today, would</p>	<p style="text-align: right;">Page 327</p> <p>1 the exact same method --</p> <p>2 MR. RESTAINO:</p> <p>3 Q. Okay.</p> <p>4 A. -- but this is what we had.</p> <p>5 Q. Correct.</p> <p>6 Now, in addition to the abstract that</p> <p>7 you are relying upon in your expert report and</p> <p>8 this article which I just handed to you, what</p> <p>9 other peer-reviewed scientific article are you</p> <p>10 relying upon that shows that polypropylene does</p> <p>11 not degrade at all in vivo?</p> <p>12 A. Where did we get -- I put based on my</p> <p>13 positive experience using the mesh products that</p> <p>14 I do.</p> <p>15 Q. Now, would you agree that your</p> <p>16 experience is anecdotal?</p> <p>17 A. Yes, it's anecdotal.</p> <p>18 Q. No control groups?</p> <p>19 A. No control groups.</p> <p>20 Q. No -- and if I recall from yesterday,</p> <p>21 you've never asked for electron microscopic</p> <p>22 examination of the explanted mesh?</p> <p>23 A. I have not.</p> <p>24 Q. So what are you relying upon to say</p>
<p style="text-align: right;">Page 326</p> <p>1 you agree that if it hasn't been replicated --</p> <p>2 well, let me strike that.</p> <p>3 In the scientific method, we go through</p> <p>4 a number of steps including hypothesis, testing,</p> <p>5 observation, conclusions, publication,</p> <p>6 replication; correct?</p> <p>7 A. Correct.</p> <p>8 Q. This is missing the critical step of</p> <p>9 replication?</p> <p>10 MR. WALKER:</p> <p>11 Object to the form.</p> <p>12 A. I don't know of any replicated studies.</p> <p>13 MR. RESTAINO:</p> <p>14 Q. Okay. Fair enough.</p> <p>15 If it has not been replicated -- let's</p> <p>16 assume for a moment it has not been replicated --</p> <p>17 then the scientific method has not been</p> <p>18 completely fulfilled and it wouldn't be generally</p> <p>19 accepted in the world of medicine and science;</p> <p>20 correct?</p> <p>21 MR. WALKER:</p> <p>22 Object to the form.</p> <p>23 A. Yeah, that may be possible if you had</p> <p>24 five studies after that that didn't show it using</p>	<p style="text-align: right;">Page 328</p> <p>1 that the mesh has not undergone degradation with</p> <p>2 particle release if it's done at such a level</p> <p>3 where the naked eye can't see it?</p> <p>4 A. Well, it's not -- I don't know whether</p> <p>5 it has specifically, but I just know it has no</p> <p>6 clinical significance. In my patients that I've</p> <p>7 seen, I've not seen a clinical significance.</p> <p>8 Q. Okay. Now if we can turn to page 29 of</p> <p>9 your expert report.</p> <p>10 MR. WALKER:</p> <p>11 You do like to jump around.</p> <p>12 A. Okay.</p> <p>13 MR. RESTAINO:</p> <p>14 Q. You're talking about mechanical and</p> <p>15 laser cut?</p> <p>16 A. Yes.</p> <p>17 Q. And you write: "The material and any</p> <p>18 particles would be the same Prolene polypropylene</p> <p>19 material used in the mesh that as discussed above</p> <p>20 is a well-tolerated, biocompatible material."</p> <p>21 Correct?</p> <p>22 A. Correct.</p> <p>23 Q. But we've already discussed that in</p> <p>24 some individuals, in some situations, a single</p>



<p style="text-align: right;">Page 329</p> <p>1 stitch can result in a foreign body reaction that  2 leads to pain requiring excision; correct?  3 A. We talked about that people spit a  4 stitch out, but not pain. I haven't noticed  5 pain. It's more discharge or something like  6 that. I never had pain with it necessarily.  7 MR. WALKER:  8 I'm sorry to interrupt.  9 MR. RESTAINO:  10 Sure.  11 MR. WALKER:  12 Have you moved on to the SUI report?  13 You said page 29?  14 A. Yeah, and I didn't see that either.  15 MR. WALKER:  16 Yeah. What -- I'm just wondering what  17 you are referring to.  18 MR. RESTAINO:  19 Okay.  20 MR. WALKER:  21 But you are asking about laser cut.  22 MR. RESTAINO:  23 Yes.  24 MR. WALKER:</p>	<p style="text-align: right;">Page 331</p> <p>1 MR. WALKER:  2 No. That's fine.  3 A. So we are on 29?  4 MR. WALKER:  5 Although, page 29 is talking about  6 warnings, so I don't know.  7 MR. RESTAINO:  8 Okay.  9 MR. WALKER:  10 Maybe you meant 39. Let's go to 39.  11 MR. RESTAINO:  12 Let's see where I got laser.  13 A. I don't think we have 39.  14 MR. WALKER:  15 No, there is not a page 39 for that  16 one.  17 MR. RESTAINO:  18 I will bring it up right here.  19 Q. On your -- are we back on?  20 On your -- your expert report for the  21 TVT and TVT-O, Abbrevia, et al., if you go to page  22 4 of the report --  23 A. Okay.  24 Q. -- and the fourth line down, talking</p>
<p style="text-align: right;">Page 330</p> <p>1 That's why I made the comment about  2 jumping around because you had been on page 39 of  3 his Prolift report.  4 MR. RESTAINO:  5 Okay. I think I'm looking at the --  6 his -- the TVT, TVT-O report.  7 MR. WALKER:  8 Okay. So he doesn't have that in  9 front of him.  10 MR. RESTAINO:  11 Q. Oh, my apologies. I should have broke  12 that down.  13 A. Are we back on that? Do you want me to  14 get that report out?  15 Q. Yes.  16 A. So we are not going to need the --  17 Q. I think we are all done with that.  18 A. Okay.  19 Q. I'm winding down here.  20 MR. WALKER:  21 That's why I was getting a little  22 confused.  23 MR. RESTAINO:  24 Yeah, my apologies.</p>	<p style="text-align: right;">Page 332</p> <p>1 about you've implanted Ethicon's mesh products  2 which are both laser cut and mechanically cut;  3 correct?  4 A. Correct. Yes.  5 Q. So let me just ask some foundational  6 questions.  7 A. Sure.  8 Q. And I apologize for missing this.  9 Stating -- reading this, then stating the  10 obvious, there are mesh products that are laser  11 cut and mechanically cut --  12 A. Correct.  13 Q. -- correct? And do you have an opinion  14 regarding why there are two different  15 methodologies?  16 A. I think it's just the way they make it.  17 Q. Okay. Do you know why they've started  18 using the laser to cut mesh?  19 A. I think it's more just technical, just  20 the way it was in the manufacturing of it.  21 Q. Have you seen any emails from within  22 Ethicon referring to the use of laser cut to  23 minimize particle degradation?  24 A. I have seen some, but I'd have to look.</p>



<p style="text-align: right;">Page 333</p> <p>1 Q. Okay.</p> <p>2 A. Do you have one?</p> <p>3 Q. I think we will get to one of those.</p> <p>4 But referring to the -- we were talking about</p> <p>5 particles and being non-reactive or not -- inert.</p> <p>6 You do mention in your expert report the study by</p> <p>7 Clavé?</p> <p>8 A. Yes.</p> <p>9 Q. Correct?</p> <p>10 A. Yes.</p> <p>11 Q. And you have some questions regarding</p> <p>12 the methodology that he utilizes?</p> <p>13 A. Okay.</p> <p>14 Q. Correct?</p> <p>15 A. Yes. I said that. Where are we?</p> <p>16 Q. I think we are on page 38.</p> <p>17 Yes, page 38 of today's report.</p> <p>18 MR. WALKER:</p> <p>19 So we are back to Prolift.</p> <p>20 A. Yes.</p> <p>21 MR. WALKER:</p> <p>22 You can look on this.</p> <p>23 MR. RESTAINO:</p> <p>24 Q. The last two sentences of the page, you</p>	<p style="text-align: right;">Page 335</p> <p>1 A. I was given Clavé, I believe. I did a</p> <p>2 PubMed review on degradation. I imagine if I saw</p> <p>3 Clavé, I knew I already had it.</p> <p>4 Q. Okay. As you sit here today, and this</p> <p>5 may be something that you know or you might have</p> <p>6 to estimate, do you -- with Clavé being published</p> <p>7 in 2010 or some seven years ago, do you know how</p> <p>8 many papers have now referenced the Clavé study?</p> <p>9 A. I'm not familiar with that.</p> <p>10 Q. Okay. So when you state that there is</p> <p>11 no extensive peer-review literature that supports</p> <p>12 this hypothesis, what's the basis for that</p> <p>13 statement?</p> <p>14 A. I imagine I had read that -- I had read</p> <p>15 that somewhere in my review of some of the</p> <p>16 literature, and I can't tell you right now off</p> <p>17 the top of my head where that is.</p> <p>18 Q. Okay. So when you say you read that,</p> <p>19 are you saying that you read someone saying that</p> <p>20 there is no extensive peer-review literature</p> <p>21 supporting this or did you read something which</p> <p>22 led you to state?</p> <p>23 A. I read something someone else had said.</p> <p>24 Q. Okay. Do you know Dr. Henri Clavé?</p>
<p style="text-align: right;">Page 334</p> <p>1 write: "In recent years ..."</p> <p>2 That's the last three sentences or so.</p> <p>3 A. Okay.</p> <p>4 Q. At the bottom of page 38.</p> <p>5 A. Uh-huh.</p> <p>6 Q. "In recent years, there have been</p> <p>7 concerns regarding polypropylene degradation ..."</p> <p>8 A. "In recent -- yes. Right.</p> <p>9 Q. "By high-magnification images that show</p> <p>10 meshes with 'cracked' surfaces."</p> <p>11 A. Correct.</p> <p>12 Q. Reference 93.</p> <p>13 "This referenced Clavé study; there</p> <p>14 were many methodological flaws."</p> <p>15 A. Right.</p> <p>16 Q. "While these purported surface changes</p> <p>17 were hypothesized to lead to adverse clinical</p> <p>18 outcomes, they cannot be confirmed, and there is</p> <p>19 no extensive peer-review literature that support</p> <p>20 this hypothesis."</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. Did you do a PubMed review finding</p> <p>24 Clavé or were you given Clavé, if you recall?</p>	<p style="text-align: right;">Page 336</p> <p>1 A. No, I do not.</p> <p>2 Q. Okay. Do you know that he has an</p> <p>3 education position for Ethicon Europe?</p> <p>4 A. Oh, I read that, yes.</p> <p>5 Q. Did you ask, can I talk with Dr. Clavé?</p> <p>6 A. No, I did not.</p> <p>7 Q. Okay. And I'd like to mark as next an</p> <p>8 email. It is Ethicon Mesh .07226481-Ethicon</p> <p>9 (Burkley) response to Clavé paper re degradation,</p> <p>10 March 2012.</p> <p>11 (Defendant's Exhibit Number 38 was</p> <p>12 marked for identification.)</p> <p>13 MR. RESTAINO:</p> <p>14 Q. And just let me know when you are</p> <p>15 finished reading.</p> <p>16 MR. WALKER:</p> <p>17 And, Counsel, this is not Bates</p> <p>18 stamped. Is this just an extracted paragraph</p> <p>19 from an email chain?</p> <p>20 MR. RESTAINO:</p> <p>21 Exactly, which is why I put into the</p> <p>22 record the Bates stamping from it. It is</p> <p>23 ETH.mesh.07226481, dated March 2012. I did this</p> <p>24 last night, and I realized I don't have the</p>

<p style="text-align: right;">Page 337</p> <p>1 actual email thread.</p> <p>2 Q. Did you have a chance to read this?</p> <p>3 A. I read it, uh-huh.</p> <p>4 Q. If you read underneath the title or</p> <p>5 the second sentence, they state: "It is our</p> <p>6 opinion that the findings published in this paper</p> <p>7 were most likely the result of the complications</p> <p>8 that necessitated removal of mesh implants. It</p> <p>9 is not unexpected that there will be an increase</p> <p>10 in free radicals and other reactive oxygen</p> <p>11 species in an infected field and/or a site of</p> <p>12 chronic inflammation."</p> <p>13 Did I read that correctly?</p> <p>14 A. Correct.</p> <p>15 Q. So this email from within Ethicon is</p> <p>16 stating that with an infection and/or chronic</p> <p>17 inflammation, the release of reactive oxygen</p> <p>18 species, this would break down the polypropylene;</p> <p>19 correct?</p> <p>20 MR. WALKER:</p> <p>21 I object to form.</p> <p>22 A. It could, but the way I read that as</p> <p>23 well is the fact that this is probably, and I</p> <p>24 don't know this for sure, related to an exposed</p>	<p style="text-align: right;">Page 339</p> <p>1 -- hang on a second. Look at tab 93. It should</p> <p>2 be at tab 93.</p> <p>3 A. That's in the other report.</p> <p>4 MR. WALKER:</p> <p>5 No, no, no. This is from your Prolift</p> <p>6 report.</p> <p>7 A. Oh, okay. Well, Prolift is over here.</p> <p>8 MR. WALKER:</p> <p>9 Yeah, let's look at that.</p> <p>10 MR. RESTAINO:</p> <p>11 We are off the record now.</p> <p>12 (Break.)</p> <p>13 MR. RESTAINO:</p> <p>14 Q. Okay. If you would turn -- well, let's</p> <p>15 go back on. And I believe before we went off the</p> <p>16 record, you were saying you're hypothesizing that</p> <p>17 it could have been the exposure?</p> <p>18 A. Correct.</p> <p>19 Q. Okay. Now, if we turn to this -- the</p> <p>20 second page, bottom left column, materials and</p> <p>21 methods.</p> <p>22 A. Second page, bottom left column.</p> <p>23 Q. Materials and methods?</p> <p>24 A. Oh, gosh. Yes.</p>
<p style="text-align: right;">Page 338</p> <p>1 mesh that's been in the vagina. So some of that</p> <p>2 inflammation and infection is because it's been</p> <p>3 exposed to the vagina and it has the bacteria and</p> <p>4 all that to go along with that versus mesh that's</p> <p>5 under the skin.</p> <p>6 Q. Now, the Clavé article is in your</p> <p>7 reference list?</p> <p>8 A. Yes. Is it? Are you asking me?</p> <p>9 Q. Is it? Yes.</p> <p>10 A. Yes.</p> <p>11 Q. If we can pull that up for a moment.</p> <p>12 MR. WALKER:</p> <p>13 Should be. In these reliances?</p> <p>14 A. It's in my list. I read this. It's in</p> <p>15 my list.</p> <p>16 MR. WALKER:</p> <p>17 Yeah, it is.</p> <p>18 MR. RESTAINO:</p> <p>19 Q. If you take a look at it, can you tell</p> <p>20 us the indications for the excision of the mesh?</p> <p>21 A. I'll have to get it. I'm going to have</p> <p>22 to -- it's in my -- I believe it's --</p> <p>23 MR. WALKER:</p> <p>24 Hang on one second. Let's look at the</p>	<p style="text-align: right;">Page 340</p> <p>1 Q. Sample collection?</p> <p>2 A. Yes.</p> <p>3 Q. "This prospective comparative study</p> <p>4 included 100 prosthetic explants surgically</p> <p>5 removed for one (or several) common -- going up</p> <p>6 to the top -- complications including exposure,</p> <p>7 infection, and/or shrinkage."</p> <p>8 A. Yep.</p> <p>9 Q. Did I read that correctly?</p> <p>10 A. Yes, and in the results it says that</p> <p>11 46 percent were from exposures.</p> <p>12 Q. Which would leave the remainder, so</p> <p>13 54 percent, 54 percent or so, that were not due</p> <p>14 to exposure, so therefore not exposed to air;</p> <p>15 correct?</p> <p>16 A. Except they said that it was isolated,</p> <p>17 that 17 percent were isolated infections. Only</p> <p>18 14 percent were for pain.</p> <p>19 Q. And for those with pain --</p> <p>20 A. That's definitely under the skin.</p> <p>21 Q. Okay. Now, we can move on from there.</p> <p>22 A. Okay. You don't need Clavé anymore?</p> <p>23 Q. Don't need Clavé anymore.</p> <p>24 A. Okay.</p>

<p style="text-align: right;">Page 341</p> <p>1 Q. We did that.</p> <p>2 If you would -- now we are going to be</p> <p>3 on your expert report for today.</p> <p>4 A. Okay.</p> <p>5 Q. TVT and TVT-O, et cetera.</p> <p>6 A. I got it.</p> <p>7 MR. WALKER:</p> <p>8 Just give it to me.</p> <p>9 A. Damn. Excuse me. All right. Let's go</p> <p>10 to TVT. Got it.</p> <p>11 You're through with the email; right?</p> <p>12 MR. RESTAINO:</p> <p>13 Q. Yes.</p> <p>14 A. Through with the email. Got you.</p> <p>15 Okay. Got you.</p> <p>16 Q. I'm going through things we've already</p> <p>17 discussed, so I'm skipping questions.</p> <p>18 In your general and supplemental</p> <p>19 reliance list, you have an article, Brubaker,</p> <p>20 B-R-U-B-A-K-E-R, titled "Adverse Events Over Two</p> <p>21 Years after Retropubic or Transobturator</p> <p>22 Midurethral Sling Surgery: Findings from the</p> <p>23 Trial of Midurethral Sling (TOMUS) Study."</p> <p>24 Do you recall that?</p>	<p style="text-align: right;">Page 343</p> <p>1 meta-analysis, is the top of the pyramid?</p> <p>2 A. Correct.</p> <p>3 Q. As you sit here today after doing your</p> <p>4 review, do you recall why you did not include</p> <p>5 this randomized controlled trial in your expert</p> <p>6 report of midurethral slings?</p> <p>7 A. I don't recall. I just -- this was a</p> <p>8 total of, let's see here, 597 women, which is a</p> <p>9 nice size study, but I have lots of studies with</p> <p>10 lots bigger numbers than that.</p> <p>11 Q. Okay.</p> <p>12 A. There is a lot of literature out there</p> <p>13 included and not included, so --</p> <p>14 Q. Okay. If you look at the abstract and</p> <p>15 the objectives, they write: "To describe</p> <p>16 surgical complications in 597 women over a</p> <p>17 24-month period following randomization to</p> <p>18 retropubic or transobturator midurethral slings."</p> <p>19 Correct?</p> <p>20 A. Yes.</p> <p>21 Q. So we've got a randomized controlled</p> <p>22 trial, a long term of 24 months, and by</p> <p>23 definition, randomized; correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 342</p> <p>1 A. I recall the study, but I need to</p> <p>2 refresh myself. Let's see where --</p> <p>3 Q. I have a copy of it here for you if</p> <p>4 you'd like.</p> <p>5 A. Great. Thanks.</p> <p>6 (Defendant's Exhibit Number 39 was</p> <p>7 marked for identification.)</p> <p>8 A. Okay.</p> <p>9 MR. RESTAINO:</p> <p>10 Q. Now, this paper is not referenced in</p> <p>11 your expert report; correct?</p> <p>12 A. I don't know. I don't remember. I</p> <p>13 don't remember -- I don't remember seeing this</p> <p>14 off the top of my head, but --</p> <p>15 Q. Okay. Looking at the title there,</p> <p>16 TOMUS stands for the Trial of Midurethral Slings;</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. And that's what we are discussing</p> <p>20 today?</p> <p>21 A. Correct.</p> <p>22 Q. And it's a randomized controlled trial?</p> <p>23 A. Yes.</p> <p>24 Q. Which, as we discussed, other than a</p>	<p style="text-align: right;">Page 344</p> <p>1 Q. Now, on page 5, going on to page 6 of</p> <p>2 the study, the last sentence --</p> <p>3 A. Page 6 of the study.</p> <p>4 Q. Page 5, going on to page 6.</p> <p>5 A. Got you. Let's see here.</p> <p>6 Okay.</p> <p>7 Q. They write: "Two years</p> <p>8 post-operatively ..."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 "The retropubic procedures demonstrate</p> <p>13 higher rates of voiding dysfunction and UTI,</p> <p>14 while the transobturator procedures were</p> <p>15 associated with higher rates of transient</p> <p>16 neurological symptoms?"</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. So, for the record, can you tell us</p> <p>20 what a UTI is?</p> <p>21 A. A bladder infection.</p> <p>22 Q. Okay. And then when they say transient</p> <p>23 neurological systems, what is meant by transient?</p> <p>24 A. It lasted -- it was not prolonged.</p>

<p style="text-align: right;">Page 345</p> <p>1 Q. Okay. And then if you'd look on page 2 7, and there is a table, Table 1? 3 A. Yes. 4 Q. If you look at the third line of the 5 table, there is a listing for bladder 6 perforation. 7 A. Yes. 8 Q. And what is that? 9 A. That's when usually in a retropubic 10 sling, it's -- the trocar is placed through the 11 bladder. 12 Q. And that would typically involve 13 urethral or suprapubic catheterization or 14 surgical correction? 15 A. It depends. Usually it would require 16 just prolonged catheter placement and it heals 17 itself. 18 Q. Okay. So for the lay person, this is a 19 hole in the bladder? 20 A. It's a hole in the bladder by a trocar 21 that's about 5 millimeters, a very small hole. 22 Usually it's through and through and both of 23 those will heal spontaneously with bladder rest. 24 Q. Okay. Which is the catheter?</p>	<p style="text-align: right;">Page 347</p> <p>1 Do you see that, sir? 2 A. Yes. 3 Q. Three percent of the patients receiving 4 TVT sustained this adverse event versus again 5 zero with the TVT-O? 6 A. Yes. 7 Q. And this was a statistically 8 significant finding? 9 A. Correct. 10 Q. Do you know if the 3 percent versus 0 11 percent incidence rate is listed in the IFU? 12 A. I'm not familiar. I would have to 13 look. 14 Q. Okay. Is it safe to say these 15 incidences are not listed in your expert report 16 because this study is not in your expert report? 17 Correct? 18 A. That's safe to say. 19 Q. Okay. Two lines below the line 20 describing the voiding dysfunction with the TVT 21 line is a line titled "Total SAEs," small s. 22 Did I read that correctly? 23 A. Correct. 24 Q. So, I'm sorry. It's capital S-A-E,</p>
<p style="text-align: right;">Page 346</p> <p>1 A. Just a catheter. 2 Q. Okay. So in this study and this table, 3 5 percent of the patients receiving the TVT 4 retropubic device sustained a perforated bladder 5 as compared to 0 percent receiving the TVT-O 6 device; is that correct? 7 A. That's correct. 8 Q. And this is a statistically significant 9 finding? 10 A. Yes. 11 Q. Now, as you sit here today, do you know 12 if the 5 percent versus 0 percent incidence of 13 bladder perforation observed with the TVT from 14 the TOMUS randomized controlled trial is listed 15 in the IFU? 16 A. As I sit here today, I do not know 17 that. 18 Q. Okay. 19 A. I would have to review the IFU. 20 Q. The same table, midway down, 21 highlighted on the top and bottom by thick black 22 lines, there is a line titled "Voiding 23 Dysfunction Requiring Surgery (and/or Catheter 24 Use)."</p>	<p style="text-align: right;">Page 348</p> <p>1 small s. And do you understand SAE to stand for 2 Serious Adverse Events? 3 A. Yes. 4 Q. And so that's as compared to AE for an 5 adverse event; correct? 6 A. Correct. 7 Q. So 15.4 percent of all patients in the 8 TOMUS randomized controlled trial who received a 9 TVT sustained a serious adverse event as defined 10 by these authors; agreed? 11 A. Yeah, that's what this says. I'm not 12 familiar with what the serious adverse event is. 13 Q. Okay. And that's as compared to 14 8.7 percent of the patients in the TOMUS RCT 15 receiving the TVT-O; correct? 16 A. Yes. 17 Q. And I will represent to you when I use 18 my slide ruler, that there is a 77 percent 19 increased incidence of SAEs, serious adverse 20 events, with the TVT device in this randomized 21 controlled trial as compared to the TVT-O. 22 A. How did you get 77 percent? 23 Q. I don't remember. I think I divided -- 24 I think I divided the 8.7 by 15.4, multiplied by</p>

<p style="text-align: right;">Page 349</p> <p>1 a 100.</p> <p>2 A. Okay.</p> <p>3 Q. You know, in case my math is wrong,</p> <p>4 would you agree that there is an increased risk</p> <p>5 in the --</p> <p>6 A. Yes.</p> <p>7 Q. Okay.</p> <p>8 A. I would agree with that.</p> <p>9 Q. Because, you know, slide rulers are,</p> <p>10 you know, a little bit difficult to handle.</p> <p>11 A. Got you.</p> <p>12 Q. Now, this was a statistically</p> <p>13 significant finding?</p> <p>14 A. Yes.</p> <p>15 Q. So therefore it's unlikely to be due to</p> <p>16 chance?</p> <p>17 A. Yes.</p> <p>18 Q. Do you know the -- whatever percent</p> <p>19 increased incidence of SAE associated with the</p> <p>20 TVT as pointed out here, do you know if that</p> <p>21 incidence is listed in the IFU for surgeons to</p> <p>22 see?</p> <p>23 A. I am not -- as I sit here now, I'm not</p> <p>24 sure.</p>	<p style="text-align: right;">Page 351</p> <p>1 Q. I don't know either.</p> <p>2 A. Yeah.</p> <p>3 Q. Now, the reference here is Ford, et al.</p> <p>4 "Midurethral Sling Operations for Stress Urinary</p> <p>5 Incontinence in Women," from the Cochrane</p> <p>6 database, "a Systematic Review"; is that correct?</p> <p>7 A. Where are you seeing that? Oh, there?</p> <p>8 Q. Yeah, the actual reference for that.</p> <p>9 A. Yep. Here it is, number 39.</p> <p>10 Q. Okay.</p> <p>11 A. I have it.</p> <p>12 Q. Do you have that study?</p> <p>13 A. Yep.</p> <p>14 MR. WALKER:</p> <p>15 Hang on.</p> <p>16 A. Here it is.</p> <p>17 MR. WALKER:</p> <p>18 It's going to be earlier in your</p> <p>19 report.</p> <p>20 A. 2015, right? This is Cochrane?</p> <p>21 MR. RESTAINO:</p> <p>22 Q. 2015.</p> <p>23 A. "Midurethral Sling Operations for</p> <p>24 Stress Urinary Incontinence in Women, Review."</p>
<p style="text-align: right;">Page 350</p> <p>1 Q. Okay. We can put that down now and</p> <p>2 move on to page 17 of your report.</p> <p>3 A. Yep.</p> <p>4 Q. And I apologize. I didn't write down</p> <p>5 where you write this, but you start writing: "In</p> <p>6 2015, Ford and colleagues ..."</p> <p>7 Do you see that?</p> <p>8 A. Yep.</p> <p>9 Q. Okay.</p> <p>10 "Published a Cochrane review on</p> <p>11 midurethral slings in women. They analyzed</p> <p>12 randomized or quasi-randomized controlled trials</p> <p>13 in which both trial arms involved the midurethral</p> <p>14 sling, including 81 trials that evaluated 12,113</p> <p>15 women?"</p> <p>16 Did I read that correctly?</p> <p>17 A. You did.</p> <p>18 Q. Before moving on to that, do you --</p> <p>19 what do you mean by quasi-randomized?</p> <p>20 A. That was the literature. I mean, that</p> <p>21 was -- I got -- took that from the report, that</p> <p>22 they said that some of it was -- I don't know</p> <p>23 exactly how they came up with quasi, but that was</p> <p>24 their word, not mine.</p>	<p style="text-align: right;">Page 352</p> <p>1 Q. Same one.</p> <p>2 A. Okay.</p> <p>3 Q. Okay. Now, this review found the</p> <p>4 slings were effective in curing incontinence at</p> <p>5 least in the short and medium term with about</p> <p>6 80 percent of women becoming dry, 70 percent</p> <p>7 remaining so 5 years later; is that correct?</p> <p>8 A. Correct.</p> <p>9 Q. But the adverse events were different</p> <p>10 in the two groups, were they not?</p> <p>11 A. Yes. I believe they were.</p> <p>12 Q. Women who had a retropubic sling were</p> <p>13 more likely to have bladder perforation --</p> <p>14 A. Correct.</p> <p>15 Q. -- at the time of surgery?</p> <p>16 A. Correct.</p> <p>17 Q. That's by the nature of the procedure?</p> <p>18 A. Correct.</p> <p>19 Q. Transobturator slings are more likely</p> <p>20 to be associated with pain in the groin or leg?</p> <p>21 A. Correct.</p> <p>22 Q. Why is that?</p> <p>23 A. Because it's a different approach. You</p> <p>24 actually go through the groin to -- the</p>



<p style="text-align: right;">Page 353</p> <p>1 retropubic approach is on either side of the  2 urethra, goes up through the symphysis pubis,  3 behind the symphysis pubis. This goes out  4 through the obturator membrane and through the  5 leg.  6 Q. Okay. Women are less likely to develop  7 difficulty voiding with the transobturator sling,  8 but more likely to need repeat surgery because of  9 recurrent incontinence. Would you agree with  10 that?  11 A. Yes, but those numbers are close.  12 Q. Okay. Now, these authors wrote: "A  13 major shortcoming of the trials is that very few  14 of them reported outcomes beyond the first year."  15 Is that correct?  16 A. Yes. I read that, yes.  17 Q. And we've discussed that already. In  18 fact, 35 of the 84 trials included in the review  19 were conducted sufficiently long ago to have  20 provided information about long-term leakage and  21 adverse effects of five years, but only four  22 actually did so. Did you see that?  23 A. I saw that.  24 Q. Okay. Now --</p>	<p style="text-align: right;">Page 355</p> <p>1 that for yourself? Do you see study selection?  2 A. Yes.  3 Q. And they write: "Retrospective,  4 cohort, prospective nonrandomized studies and  5 RCTs of women who had undergone RP-MUS or all  6 TO-MUS (including TVT-O and TOT) --  7 A. Uh-huh.  8 Q. -- "as the primary procedure for SUI  9 with a mean or median follow-up of at least  10 36 months for TO-MUS and at least 60 months for  11 RP-MUS were included."  12 Did I read that correctly?  13 A. Yes.  14 Q. So, now, the studies that were  15 retrospective, they would not be randomized  16 controlled trials; correct?  17 A. Correct.  18 Q. Now, if you turn to the third page,  19 which is page 1255 --  20 A. Yes.  21 Q. -- in the left column, they have the  22 results; correct?  23 A. Correct.  24 Q. And in the second paragraph, they</p>
<p style="text-align: right;">Page 354</p> <p>1 A. Those are -- not to -- those are  2 difficult to do sometimes, to get the studies to  3 go longer, and when you are looking at so many  4 studies out there. It's a big ordeal for people  5 to -- for the people to get back with them and  6 keep reviewing and call patients and those kind  7 of things. Those are difficult sometimes to do.  8 Q. Okay. On page 18 of your report --  9 A. Uh-huh.  10 Q. -- you talk about a Tommaselli,  11 T-O-M-M-A-S-E-L-L-I?  12 A. Uh-huh.  13 Q. Do you recall that study?  14 A. Yes, I do. Uh-huh.  15 Q. Do you have the Tommaselli study?  16 A. I do. It's number 40. Yeah. Uh-huh.  17 I've got it.  18 Q. And if you look at the second page, the  19 articles page, 1254 --  20 A. Yep.  21 Q. -- on the right column, they have study  22 selection?  23 A. Correct.  24 Q. Do you want to take a moment and open</p>	<p style="text-align: right;">Page 356</p> <p>1 write: "There were 11 RCTs."  2 Do you see that?  3 A. Correct.  4 Q. And then they give you the references.  5 "And 38 nonrandomized studies including  6 prospective, retrospective, and cohort studies  7 with references with a total of 6,406 patients  8 (1,200 in RCTs and 5,206 in nonrandomized  9 studies) age 19 to 89."  10 Did I read that correctly?  11 A. Yes.  12 Q. So, now, Tommaselli, as he states here,  13 he's reporting on -- at least with the RCTs,  14 there are 11 with a total of 1200 patients?  15 A. Correct.  16 Q. So while the entire study, as you point  17 out, involved a large number, there's 1200 in the  18 -- in RCTs; correct?  19 A. Correct. Yes.  20 Q. Now, if you'd look at table 3 on page  21 1258.  22 A. Okay. Table 3. Got it. Uh-huh.  23 Q. Now, if you look at the TVT-O patients  24 in the RCTs --</p>



<p style="text-align: right;">Page 357</p> <p>1 A. Uh-huh.</p> <p>2 Q. -- there is a --</p> <p>3 A. TVT-O. Okay.</p> <p>4 Q. TVT-O, there's a total of 459 patients.</p> <p>5 A. Let's see. All studies, 1300. 459,</p> <p>6 right.</p> <p>7 Q. So as far as what's related to this</p> <p>8 litigation with the TVT-O, even though this study</p> <p>9 includes thousands of women, there's 459 with a</p> <p>10 TVT-O?</p> <p>11 A. Correct.</p> <p>12 Q. Now, on the third page on 1255 in the</p> <p>13 right column --</p> <p>14 A. 1255?</p> <p>15 Q. 1255.</p> <p>16 A. Uh-huh.</p> <p>17 Q. -- you see they have cure and success</p> <p>18 rate in the second paragraph?</p> <p>19 A. Yes. I have, uh-huh.</p> <p>20 Q. Second paragraph, they write: "There</p> <p>21 were no RCTs comparing TVT-O with TOT in which</p> <p>22 objective outcomes were reported, while a single</p> <p>23 study, reference 14, showed similar odds of</p> <p>24 subjective cure with odds ratio and confidence</p>	<p style="text-align: right;">Page 359</p> <p>1 -- this is -- TVT and TVT-O are both obturator</p> <p>2 reports. I think this is -- I thought this -- I</p> <p>3 read this as comparing between the TVT-O and the</p> <p>4 TOT, the different approaches, not necessarily</p> <p>5 the procedure itself. You understand what I'm</p> <p>6 saying?</p> <p>7 Q. I think so, but regardless of the</p> <p>8 procedures themselves, these authors are saying</p> <p>9 that the -- that the number of RCTs in the medium</p> <p>10 term are limited and objective cure rates were</p> <p>11 not reported in any of them?</p> <p>12 A. That's what it says, yes.</p> <p>13 Q. Okay. We can go back to your expert</p> <p>14 report now. We are close.</p> <p>15 A. Okay. What you got?</p> <p>16 Q. Page 18. Your last paragraph, you talk</p> <p>17 about the Society of Gynecological Surgeons?</p> <p>18 A. Yes. 18, yes.</p> <p>19 Q. Page 18.</p> <p>20 A. Uh-huh.</p> <p>21 Q. You write: "In 2014 --</p> <p>22 In the last paragraph, okay?"</p> <p>23 A. Right.</p> <p>24 Q. "-- the Society of Gynecologic</p>
<p style="text-align: right;">Page 358</p> <p>1 interval."</p> <p>2 Correct?</p> <p>3 A. Correct.</p> <p>4 Q. So the odds ratio of 1.08 shows an</p> <p>5 8 percent difference; correct?</p> <p>6 A. Correct.</p> <p>7 Q. And it's not statistically significant,</p> <p>8 is it?</p> <p>9 A. Correct.</p> <p>10 Q. So now if you'd turn to page 1262 of</p> <p>11 the study.</p> <p>12 A. Okay.</p> <p>13 Q. The second paragraph in the right</p> <p>14 column starts with the number of RCTs?</p> <p>15 A. Uh-huh.</p> <p>16 Q. "Comparing TVT-O and TOT in the medium</p> <p>17 term, our limited and objective cure rates were</p> <p>18 not reported in any of the studies."</p> <p>19 Did I read that correctly?</p> <p>20 A. Correct.</p> <p>21 Q. So this would be lack of scientific</p> <p>22 support for objective cure rates regarding the</p> <p>23 TVT-O; wouldn't you agree?</p> <p>24 A. Well, let's see. This just talks about</p>	<p style="text-align: right;">Page 360</p> <p>1 Surgeons' Systematic Review Group published a</p> <p>2 systematic review and metaanalysis of randomized</p> <p>3 controlled trials with a minimum of one year of</p> <p>4 follow-up comparing a sling procedure to another</p> <p>5 sling procedure or a Burch procedure."</p> <p>6 Did I read that correctly?</p> <p>7 A. Yes.</p> <p>8 Q. And on page 19, you list a reference</p> <p>9 41, which is the Schimpf?</p> <p>10 A. Schimpf. I got it.</p> <p>11 Q. Okay. We will go ahead and mark</p> <p>12 Schimpf. I had a lot of trouble stapling this</p> <p>13 booger.</p> <p>14 MR. WALKER:</p> <p>15 You sure did.</p> <p>16 MR. RESTAINO:</p> <p>17 Yeah. Let me use this one for the</p> <p>18 record, okay?</p> <p>19 (Defendant's Exhibit Number 40 was</p> <p>20 marked for identification.</p> <p>21 MR. RESTAINO:</p> <p>22 Q. Looking at the Schimpf, titled "Sling</p> <p>23 Surgery for Stress Urinary Incontinence in Women:</p> <p>24 A Systematic Review and Metaanalysis," in the</p>

<p style="text-align: right;">Page 361</p> <p>1 abstract under results, do you see where they 2 write: "For midurethral slings, (MUS) vs Burch, 3 metaanalysis of objective cure showed no 4 significant difference, (OR, 1.18; 95 percent 5 confidence interval)." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Now, at the top of the abstract, in the 9 right column, they write: "For obturator slings 10 vs retropubic MUS, metaanalyses for both 11 objective (odds ratio, 1.16; 95 percent 12 confidence interval, 0.93-1.45) and subjective 13 cure (odds ratio, 1.17; 95 percent confidence 14 interval, 0.91-1.51) favored retropubic slings 15 but were not significant." 16 Correct? 17 A. Correct. 18 Q. And that's not significant because each 19 confidence interval includes unity or is less 20 than 1.0? 21 A. Right. 22 Q. So when you wrote that the -- that this 23 article coming from the Society of Gynecological 24 Surgeons' Systematic Review Group talked about</p>	<p style="text-align: right;">Page 363</p> <p>1 postoperative voiding dysfunction and de novo 2 urgency symptoms." 3 And did I read that correctly? 4 A. Yes. 5 Q. What are traditional suburethral 6 slings? 7 A. Would be a rectus sling, autologous 8 sling. 9 Q. Using the patient's own tissue? 10 A. The patient's own tissue. 11 Q. Okay. So that the -- what you write is 12 that the minimally invasive synthetic midurethral 13 sling surgery appeared to be as effective as 14 these autologous slings; correct? 15 A. Yes. 16 Q. But with the MUS, the minimally 17 invasive midurethral slings, there was a shorter 18 operative time? 19 A. Correct. 20 Q. Why is that? 21 A. Because to harvest a fascial sling, it 22 takes a long time. It's a big incision, takes a 23 much longer period of time to do the procedure. 24 Q. And the fascial sling comes from</p>
<p style="text-align: right;">Page 362</p> <p>1 the 1-year follow-up comparing a sling to another 2 sling, that would be the TVT-0 versus TVT? 3 A. Correct. 4 Q. And so those findings were not 5 statistically significant; correct? 6 A. Correct. 7 Q. And were the findings significant for 8 midurethral slings versus Burch? 9 A. As far as cure rates, according to 10 this study, no. 11 Q. Okay. 12 A. They were both very successful. 13 Q. Okay. Now we can turn to page 20 of 14 your report. I'm sorry. 15 A. I'm sorry. Page what, now? 16 Q. Page 20 of your report. 17 A. Okay. 18 Q. You write: "In 2011, OGAH, O-G-A-H, 19 and colleagues published a short version Cochrane 20 review that analyzed 62 studies involving 7,101 21 women. They found that minimally invasive 22 synthetic midurethral sling surgery appeared to 23 be as effective as traditional suburethral 24 slings, but with shorter operative time and less</p>	<p style="text-align: right;">Page 364</p> <p>1 removal of the fascia -- 2 A. Of the abdominal fascia. And it's from 3 the rectus fascia, so you have to make an 4 incision here, take the fascia, then make 5 incisions here and get around it. It's a big 6 procedure. I've done one in my life. 7 Q. Okay. Do you have the OGAH paper? 8 A. Yes. 9 Q. If we can take a look at that. 10 A. Okay. 11 Q. And their abstract starts with 12 background? 13 A. Yeah. 14 Q. Okay. And then midway, roughly, in the 15 paragraph, they talk about results? 16 A. Yes. 62 trials. 17 Q. Involving 7,101 women were included; 18 correct? 19 A. Yes. 20 Q. The quality of evidence was moderate 21 for most trials? 22 A. Correct. 23 Q. Minimally invasive synthetic 24 suburethral sling operations appeared to be as</p>

<p style="text-align: right;">Page 365</p> <p>1 effective as traditional suburethral slings. And  2 that's the language you use in your report;  3 correct?  4 A. Yes.  5 Q. And there they state -- right after  6 that, they reference eight trials, and 599, risk  7 ratio of 1.03, 95 percent confidence interval of  8 0.94 to 1.3; correct?  9 A. Correct.  10 Q. So while the entire study involves  11 7,101, the minimally invasive synthetic  12 suburethral sling operations involved 599;  13 correct?  14 A. Yes.  15 Q. And the risk ratio of 1.03 would  16 indicate a 3 percent difference?  17 A. Yes.  18 Q. And the confidence interval includes  19 unity, so it's not even statistically  20 significant?  21 A. It says 1.13 confidence interval, yeah.  22 Q. 0.94 to 1.3?  23 A. Yeah. Yeah.  24 Q. And the 0.94 is less than 1.0 --</p>	<p style="text-align: right;">Page 367</p> <p>1 appeared to be as effective as open retropubic  2 colposuspension, but the confidence interval  3 shows us that at the short-term, it wasn't  4 statistically significant, and at 5 years, it's  5 not statistically significant?  6 A. But the actual procedure is a lot less  7 complicated.  8 Q. But the procedure is less complicated  9 but may be no more effective?  10 A. May be no more effective.  11 Q. All right. We can turn to page 21 of  12 your report.  13 A. Uh-huh.  14 Q. Two pages. And you talk about Unger,  15 Unger and colleagues?  16 A. Yes. Where are we? 21?  17 MR. WALKER:  18 Right here.  19 MR. RESTAINO:  20 Q. Okay. Yeah.  21 "Unger and colleagues reported the  22 results of their case controlled study of all  23 women who received midurethral slings for SUI  24 between January 2003 and December 10th, 2013."</p>
<p style="text-align: right;">Page 366</p> <p>1 A. Sure.  2 Q. -- so it's --  3 A. Okay.  4 Q. So chance cannot be ruled out as being  5 the cause of this finding; correct?  6 A. Correct.  7 Q. Then another two lines down, they  8 write: "Minimally invasive synthetic suburethral  9 sling operations appeared to be as effective as  10 open retropubic colposuspension (subjective cure  11 rate at 12 months, relative risk, 0.96, 95  12 percent confidence interval, 0.90-1.03, and at  13 5 years, relative risk, 0.91, 95 percent  14 confidence interval, 0.74-1.2) with fewer  15 perioperative complications, less postoperative  16 voiding dysfunction, shorter operation time,  17 hospital stay, but significantly more bladder  18 perforations (6 percent versus 1 percent, a  19 relative risk of 4.124, 95 percent confidence  20 interval of 1.71 to 10.52."  21 Did I read that all correctly?  22 A. Yes.  23 Q. So to break it down, the minimally  24 invasive synthetic suburethral sling operations</p>	<p style="text-align: right;">Page 368</p> <p>1 Correctly -- correct?  2 A. Yes.  3 Q. And the overall rate of sling revision  4 after midurethral sling placement was 2.72?  5 2.7 percent; correct?  6 A. Underwent sling placement and 2.7  7 underwent sling revision for --  8 Q. I think I -- I've got it written down,  9 but it's on the next page?  10 A. Yeah. Yeah.  11 Q. The overall rate of sling revision was  12 2.7 percent?  13 A. Correct.  14 Q. Do you have the Unger paper?  15 A. Yes. Yes.  16 Q. I will pull it up myself, now we are at  17 the end. This is what I was doing late last  18 night and I didn't write down where I got it  19 from.  20 A. We will find it.  21 Q. Where did I get that? I'm sorry.  22 Okay. On the very last page of the Unger  23 study --  24 A. Okay.</p>

<p style="text-align: right;">Page 369</p> <p>1 Q. -- there is a large paragraph there.  2 About midway down, you see the 2.7 percent  3 figure?  4 A. Yes, uh-huh.  5 Q. But they write: "As a result, our  6 incidence rate of 2.7 percent may be an  7 underestimate of the true rate of revision  8 surgery after midurethral sling at our  9 institution."  10 Do you see that, sir?  11 A. Yes.  12 Q. So when you wrote that they have a 2.7  13 percent revision rate, your expert report doesn't  14 include that it might be an underestimation of  15 the actual rate; would you agree?  16 A. I agree. It does not say that.  17 Q. Okay. Now we are on to the very last  18 section.  19 MR. RESTAINO:  20 I don't have any more questions.  21 MR. WALKER:  22 Let's go off the record for a minute.  23 (Break.)  24 EXAMINATION</p>	<p style="text-align: right;">Page 371</p> <p>1 Q. And based on your experience and your  2 discussions with your other colleagues, your  3 review of the medical literature, are doctors  4 implanting mesh familiar with this phenomenon of  5 scar tissue causing some degree of mesh  6 contracture in a patient?  7 A. Yes.  8 Q. And in your experience, have you seen  9 mesh shrinkage or contraction to be a clinically  10 significant problem that would cause you to  11 question the safety or efficacy of the Gynemesh  12 PS mesh or the Ultrapro mesh used in Prolift+M?  13 A. I have not seen that in my experience.  14 Q. And, Doctor, you were asked a number of  15 -- strike that.  16 Many times throughout yesterday and  17 today's deposition, when questioned on the  18 various pieces of medical literature, you've been  19 asked what the follow-up was on that study?  20 A. That's correct.  21 Q. Do you recall those questions?  22 A. Yes.  23 Q. And many of the pieces of medical  24 literature that you cite in your report and are</p>
<p style="text-align: right;">Page 370</p> <p>1 BY MR. WALKER:  2 Q. Doctor, I want to first ask you a  3 couple of follow-up questions --  4 A. Sure.  5 Q. -- on the issue of mesh shrinkage and  6 contraction.  7 A. Okay.  8 Q. Do you remember that discussion from  9 yesterday?  10 A. Yes.  11 Q. And, Doctor, your opinion, as you  12 articulated yesterday and in your report, is that  13 mesh itself does not contract or shrink, but it's  14 the tissue that's acting on the mesh that would  15 cause the contracture or shrinkage; is that  16 correct?  17 A. That is my statement.  18 Q. And is scar tissue contracture a  19 commonly known phenomenon following any type of  20 vaginal surgery?  21 A. Yes.  22 Q. And when I say commonly known, I mean  23 in regards to what pelvic surgeons understand?  24 A. Absolutely.</p>	<p style="text-align: right;">Page 372</p> <p>1 on your reliance list have follow-ups that are  2 less than two years; is that fair?  3 A. That's correct.  4 Q. And there is also literature that you  5 cite in your report and on your reliance list  6 that shows follow-ups beyond two years as well;  7 is that correct?  8 A. That's correct.  9 Q. And you've relied on both sets of  10 literature in formulating your opinion; correct?  11 A. That's correct.  12 Q. And that would be true for both your  13 prolapse and your SUI reports?  14 A. Yes.  15 Q. But with regards to studies that have  16 follow-ups of less than one year, this would  17 include randomized controlled trials; correct?  18 A. Yes. Good studies, just not a lot of  19 follow-up.  20 Q. And in addition to randomized  21 controlled trials, are there other types of  22 studies, prospective, retrospective studies --  23 A. Correct.  24 Q. -- that you've relied on? Correct?</p>

<p style="text-align: right;">Page 373</p> <p>1 A. Correct.</p> <p>2 Q. And, Doctor, do experts in your field</p> <p>3 routinely rely on randomized controlled trials</p> <p>4 and other well-performed studies that have</p> <p>5 follow-up times of less than 24 months?</p> <p>6 MR. RESTAINO:</p> <p>7 Objection.</p> <p>8 A. Yes, because that's what we have.</p> <p>9 MR. WALKER:</p> <p>10 Q. And, Doctor, you were asked questions</p> <p>11 about foreign body reactions.</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. And I believe it's your testimony that</p> <p>16 any foreign object that's placed in the body will</p> <p>17 elicit some degree of a foreign body reaction; is</p> <p>18 that correct?</p> <p>19 A. That is correct.</p> <p>20 Q. And is that something that is commonly</p> <p>21 understood by surgeons, regardless of what field</p> <p>22 of medicine they practice in?</p> <p>23 A. Yes.</p> <p>24 Q. So, the fact that a synthetic mesh is</p>	<p style="text-align: right;">Page 375</p> <p>1 A. I have not seen it in the literature</p> <p>2 and I for sure have not seen it in my medical</p> <p>3 practice.</p> <p>4 Q. You were shown a few articles today. I</p> <p>5 briefly want to touch on some of these.</p> <p>6 A. Okay.</p> <p>7 Q. First, do you recall counsel</p> <p>8 showed you this email pertaining to the Clavé</p> <p>9 study?</p> <p>10 A. Yes.</p> <p>11 Q. And I don't have the exhibit number,</p> <p>12 but you recall that?</p> <p>13 A. Yes, I do.</p> <p>14 Q. And, Doctor, you would agree that this</p> <p>15 is just apparently a one-paragraph excerpt from</p> <p>16 an email?</p> <p>17 A. Correct.</p> <p>18 Q. And you did not have the benefit of</p> <p>19 reading or reviewing the entire email chain that</p> <p>20 would have gone along with this?</p> <p>21 A. I have not seen that.</p> <p>22 Q. So the full context or conclusions of</p> <p>23 that email is something that you don't have at</p> <p>24 your disposal right now?</p>
<p style="text-align: right;">Page 374</p> <p>1 implanted and then elicits a foreign body</p> <p>2 reaction, does that mean that that mesh is</p> <p>3 inherently defective in design?</p> <p>4 A. No, it does not.</p> <p>5 Q. Does it mean it's inherently unsafe</p> <p>6 just because it's going to trigger a foreign body</p> <p>7 reaction?</p> <p>8 A. No.</p> <p>9 Q. And, in fact, is it your opinion that</p> <p>10 the mesh is designed to elicit to some degree a</p> <p>11 foreign body reaction?</p> <p>12 A. Yes.</p> <p>13 Q. And, Doctor, would you agree that if</p> <p>14 mesh was eliciting an excessive or problematic</p> <p>15 foreign body reaction, that is something that we</p> <p>16 would see across the board repeatedly both in</p> <p>17 terms of patient experiences and what's reflected</p> <p>18 in medical literature?</p> <p>19 MR. RESTAINO:</p> <p>20 Objection.</p> <p>21 A. Yes. Yes, I agree with that.</p> <p>22 MR. WALKER:</p> <p>23 Q. And have you seen that both in terms of</p> <p>24 your practice and in the medical literature?</p>	<p style="text-align: right;">Page 376</p> <p>1 A. That's correct.</p> <p>2 Q. And were not provided by counsel?</p> <p>3 A. That's correct.</p> <p>4 Q. If you have handy Exhibit 35, the</p> <p>5 article by Klinge, "Foreign Body Reaction to</p> <p>6 Meshes Used" --</p> <p>7 A. Did you give me that, John?</p> <p>8 Q. Yeah.</p> <p>9 A. He did?</p> <p>10 Q. Yeah.</p> <p>11 A. Okay.</p> <p>12 Q. And you can look on mine, if you want.</p> <p>13 A. Here it is.</p> <p>14 MR. RESTAINO:</p> <p>15 You have it?</p> <p>16 A. I don't. Oh, got you. I have it, yes.</p> <p>17 MR. RESTAINO:</p> <p>18 You have it?</p> <p>19 A. Yes.</p> <p>20 MR. WALKER:</p> <p>21 Q. All right, Doctor. This is an article</p> <p>22 from 1999; correct?</p> <p>23 A. Correct.</p> <p>24 Q. And this article is not examining</p>



<p style="text-align: right;">Page 377</p> <p>1 meshes placed vaginally; correct?</p> <p>2 A. Correct.</p> <p>3 Q. And it's not examining meshes that were</p> <p>4 deployed to treat prolapse or incontinence,</p> <p>5 rather these were meshes that were used in the</p> <p>6 treatment of abdominal wall hernias; correct?</p> <p>7 A. That is correct.</p> <p>8 Q. And if you look on the second page,</p> <p>9 Doctor -- and I will show you where I'm going.</p> <p>10 Right here.</p> <p>11 A. Got you.</p> <p>12 Q. Right column.</p> <p>13 A. Yes.</p> <p>14 Q. You see where it says: "Except for one</p> <p>15 Marlex mesh with a fistula being tested, no mesh</p> <p>16 showed macroscopic signs of infection or</p> <p>17 inflammation"? Do you see that?</p> <p>18 A. Is it under morphological study? Okay.</p> <p>19 Let's see. Yes, I see that. Yes.</p> <p>20 Q. And then if you will turn to the next</p> <p>21 page.</p> <p>22 A. Uh-huh.</p> <p>23 Q. Do you see under the results section on</p> <p>24 the right-hand column?</p>	<p style="text-align: right;">Page 379</p> <p>1 "Similar differences in foreign body reactions</p> <p>2 depending on the implanted material were reported</p> <p>3 by Beets, et al., who found reduced inflammation</p> <p>4 with a monofilament polypropylene mesh compared</p> <p>5 with a multifilament polypropylene mesh"?</p> <p>6 Do you see that?</p> <p>7 A. I see that.</p> <p>8 Q. And, Doctor, you are aware that Prolene</p> <p>9 is a monofilament polypropylene based suture?</p> <p>10 A. That is correct.</p> <p>11 Q. And so the mesh that is found in either</p> <p>12 the TVT products or Ethicon's prolapse products</p> <p>13 is comprised of monofilament suture material;</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. And Klinge is noting that monofilament</p> <p>17 mesh results in a reduced inflammation compared</p> <p>18 to multifilament mesh; correct?</p> <p>19 A. That's correct.</p> <p>20 Q. You were shown the Brubaker --</p> <p>21 A. Yes.</p> <p>22 Q. -- TOMUS study. Do you recall that?</p> <p>23 A. Yes. Uh-huh.</p> <p>24 Q. And you were asked a number of</p>
<p style="text-align: right;">Page 378</p> <p>1 A. Yes.</p> <p>2 Q. "This study looked at 17 different</p> <p>3 nonabsorbable meshes, but only two of them were</p> <p>4 Prolene meshes."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. So is it fair to say that in terms of</p> <p>8 its relevance to Prolene mesh, the study only</p> <p>9 examined two specimens?</p> <p>10 A. Correct.</p> <p>11 Q. And, Doctor, you understand that there</p> <p>12 is, and you note in your report that there is a</p> <p>13 difference between polypropylene and Prolene;</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you are aware that Prolene is</p> <p>17 polypropylene plus additives that are added to</p> <p>18 it?</p> <p>19 A. That's correct.</p> <p>20 Q. And if you will turn to page 670 of</p> <p>21 this Klinge article.</p> <p>22 A. Uh-huh.</p> <p>23 Q. And do you see the very last sentence</p> <p>24 on the right-hand column, where it reads:</p>	<p style="text-align: right;">Page 380</p> <p>1 questions about the rates of different</p> <p>2 complications, specifically UTI. Do you recall</p> <p>3 that?</p> <p>4 A. Correct. Yes, I do.</p> <p>5 Q. Two questions. Doctor, did</p> <p>6 the authors of this trial conclude that</p> <p>7 retropubic or transobturator midurethral slings</p> <p>8 are not safe?</p> <p>9 A. They did not conclude that.</p> <p>10 Q. Did they conclude that they are not</p> <p>11 effective?</p> <p>12 A. No, they did not conclude that.</p> <p>13 Q. You were shown Exhibit 36, an article</p> <p>14 by Nolfi entitled "Host Response to Synthetic</p> <p>15 Mesh in Women with Mesh Complications." Do you</p> <p>16 recall that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. I will give you a second to pull your</p> <p>19 copy.</p> <p>20 A. Yeah. Let me find that. Nolfi, right?</p> <p>21 Q. Yes.</p> <p>22 A. Yes. Got it. Uh-huh.</p> <p>23 Q. And do you see the very first sentence</p> <p>24 in the abstract --</p>



<p style="text-align: right;">Page 381</p> <p>1 A. Uh-huh.</p> <p>2 Q. -- under background?</p> <p>3 A. Correct.</p> <p>4 Q. How it notes that polypropylene meshes</p> <p>5 that are used to treat pelvic organ prolapse and</p> <p>6 stress urinary incontinence have good anatomic</p> <p>7 and functional outcomes?</p> <p>8 A. Yes.</p> <p>9 Q. Do you see that?</p> <p>10 A. Uh-huh.</p> <p>11 Q. And, then, Doctor, if you will look on</p> <p>12 the third page of this study, table 2.</p> <p>13 A. Table 2, uh-huh.</p> <p>14 Q. Do you see how it tabulates the</p> <p>15 different meshes that were examined in this</p> <p>16 study?</p> <p>17 A. Correct.</p> <p>18 Q. And you see you've got different</p> <p>19 manufacturers' meshes to include Ethicon's;</p> <p>20 correct?</p> <p>21 A. That's correct.</p> <p>22 Q. And it's broken into two columns the</p> <p>23 number of meshes that were removed due to</p> <p>24 exposure and then those that were removed due to</p>	<p style="text-align: right;">Page 383</p> <p>1 vaginal mesh, whether it's used to treat prolapse</p> <p>2 or stress urinary incontinence, has been</p> <p>3 successfully used in millions of patients</p> <p>4 worldwide?</p> <p>5 A. I would agree to that.</p> <p>6 (Defendant's Exhibit Number 41 was</p> <p>7 marked for identification.)</p> <p>8 MR. WALKER:</p> <p>9 Q. I'm marking as Exhibit 41 a study that</p> <p>10 you brought to your deposition today, Doctor,</p> <p>11 that I believe you reviewed after you wrote your</p> <p>12 expert reports in this case?</p> <p>13 A. Yes.</p> <p>14 Q. And this is a study by Bjorn Holdo,</p> <p>15 that's H-O-L-D-O, entitled "Long-Term Clinical</p> <p>16 Outcomes with the Retropubic Tension-Free Vaginal</p> <p>17 Tape Procedure Compared to Burch Colposuspension</p> <p>18 for Correcting Stress Urinary Incontinence"?</p> <p>19 A. Correct.</p> <p>20 Q. And this is a study that you have</p> <p>21 reviewed?</p> <p>22 A. Yes.</p> <p>23 Q. And I will just direct your attention</p> <p>24 -- well, first of all, this is a study looking at</p>
<p style="text-align: right;">Page 382</p> <p>1 pain. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And if you add up the Gynecare meshes,</p> <p>4 I came up with 12 different specimens that this</p> <p>5 study examined that would have been made by</p> <p>6 Ethicon.</p> <p>7 A. Right.</p> <p>8 Q. Do you agree with that?</p> <p>9 A. 12. You can just count, add these</p> <p>10 numbers up.</p> <p>11 Q. If you just add those figures up?</p> <p>12 A. Yes. Uh-huh. Yes.</p> <p>13 Q. And, Doctor, this study did not examine</p> <p>14 mesh removed from patients who had no complaints</p> <p>15 or complications; correct?</p> <p>16 A. Correct. I believe this -- yes.</p> <p>17 Q. This is only looking at mesh from</p> <p>18 patients that had a complication?</p> <p>19 A. That is correct.</p> <p>20 Q. Such as erosion or pain?</p> <p>21 A. Correct.</p> <p>22 Q. And can we agree, Doctor, that from</p> <p>23 your experience, and more importantly, from what</p> <p>24 you've read in the medical literature, that</p>	<p style="text-align: right;">Page 384</p> <p>1 retropubic TVT compared to the Burch procedure;</p> <p>2 correct?</p> <p>3 A. Correct. Yes.</p> <p>4 Q. And this is actually a study that's</p> <p>5 looking at some long-term results; correct?</p> <p>6 A. Correct, uh-huh.</p> <p>7 Q. What was the follow-up in this study?</p> <p>8 A. 12 years.</p> <p>9 Q. And what was the conclusion of the</p> <p>10 authors in this study?</p> <p>11 A. The long-term efficacy of TVT surgery</p> <p>12 was superior to that of Burch colposuspension in</p> <p>13 women with stress urinary incontinence, period.</p> <p>14 Q. And is this conclusion consistent with</p> <p>15 the opinions that are contained within your</p> <p>16 expert report?</p> <p>17 A. Yes, it is.</p> <p>18 (Defendant's Exhibit Number 42 was</p> <p>19 marked for identification.)</p> <p>20 MR. WALKER:</p> <p>21 Q. I'm marking as Exhibit Number 42 a</p> <p>22 registry study by, and I'm going to spell the</p> <p>23 last name because I have no hope of pronouncing</p> <p>24 it correctly, K-U-R-K-I-J-A-R-V-I. And it's</p>

<p style="text-align: right;">Page 385</p> <p>1 entitled "Reoperations for Female Stress Urinary 2 Incontinence, a Finnish National Register Study." 3 That was published by the European Association of 4 Urology. And, Doctor, this is an article that 5 you've read and reviewed; correct? 6 A. Correct. 7 Q. And, Doctor, can you just briefly 8 describe what the nature of the study is, what it 9 was looking at and what the follow-up was? 10 A. It was a study in the reoperation rate 11 of incontinent surgery -- after incontinent 12 surgery with the different surgery types. It was 13 a total of 38,500 women that were operated on 14 from 1987 to 2009, and outcome measures were 15 primary operations, reoperation rate, and patient 16 age and time until reoperation. 17 Q. And what were the different SUI 18 surgeries that this registry looked at? 19 A. It looked at retropubic and 20 transobturator slings as well as Burch 21 urethropexy. 22 Q. And what was the follow-up period? 23 A. Five years. This was five years, but I 24 think that it's longer than that. Sorry.</p>	<p style="text-align: right;">Page 387</p> <p>1 use in America as a guidance for our procedures. 2 Q. So is it fair to say, Doctor, that 3 their position statements are something that 4 doctors in your field would rely on in their 5 practice? 6 MR. RESTAINO: 7 Objection. 8 A. We would rely on it very strongly, and, 9 in fact, if they told us not to do something with 10 large -- with good data to support why you would 11 recommend not doing something, we would not. 12 MR. WALKER: 13 Q. And you mentioned good data. Just so 14 the record is clear, Doctor, would you agree that 15 there have been literally thousands of studies 16 conducted on polypropylene based midurethral 17 slings to treat stress urinary incontinence? 18 A. Yes. It looks like greater than 2000 19 publications. 20 Q. And that's according to the Position 21 Statement? 22 A. Correct. 23 Q. All right. And the statement doesn't 24 address prolapse, but let me just ask you this:</p>
<p style="text-align: right;">Page 386</p> <p>1 10-year. At 5- and 10-year follow-up. Sorry. 2 Q. And what were the conclusions of this 3 registry study? 4 A. The reoperation rate is lower after 5 midurethral slings compared with Burch 6 colposuspension. 7 Q. And is that data and that conclusion 8 consistent with the opinions that are found in 9 your expert report? 10 A. Yes, it is. 11 (Defendant's Exhibit Number 43 was 12 marked for identification.) 13 MR. WALKER: 14 Q. I'm going to mark as Exhibit Number 43 15 the Position Statement issued by AUGS and SUFU 16 from 2016. Doctor, is this a statement that you 17 are familiar with? 18 A. Yes, I am. 19 Q. And you've read it; correct? 20 A. Correct. 21 Q. And, Doctor, what are AUGS and SUFU? 22 A. These are reconstructive surgery and 23 urogynecology societies that are what we use as 24 -- who usually place most of the studies that we</p>	<p style="text-align: right;">Page 388</p> <p>1 Would you also agree that there are at least 2 hundreds of studies that have been performed 3 evaluating Prolene mesh or polypropylene mesh 4 used to repair pelvic organ prolapse? 5 A. Yes. 6 Q. And out of the 2000 studies that have 7 examined the slings, would you agree that there 8 have been hundreds of randomized controlled 9 trials over the years that have examined safety 10 and efficacy of midurethral slings? 11 MR. RESTAINO: 12 Objection. 13 A. Yes. 14 MR. WALKER: 15 Q. And we've talked about various 16 systematic reviews that have also looked at 17 midurethral slings in terms of their safety and 18 efficacy; correct? 19 A. Yes. 20 Q. Doctor, if you will turn to the last 21 page or next to last page of the AUGS/SUFU 22 Position Statement, you will see that there are a 23 number of additional organizations that have 24 endorsed that statement.</p>

<p style="text-align: right;">Page 389</p> <p>1 A. Yes.</p> <p>2 Q. And ACOG is one of them?</p> <p>3 A. Correct. Yes.</p> <p>4 Q. And is there any significance of ACOG's</p> <p>5 endorsement?</p> <p>6 A. That's very important as an</p> <p>7 obstetrician and a fellow of the American College</p> <p>8 of OB/GYN. Their statement is important to us.</p> <p>9 Q. Doctor, are your opinions regarding</p> <p>10 polypropylene, Prolene and the TVT products that</p> <p>11 are used to treat stress urinary incontinence</p> <p>12 consistent with the statements that are contained</p> <p>13 in this AUGS/SUFU Position Statement?</p> <p>14 A. Yes.</p> <p>15 Q. If I could look at that, since we only</p> <p>16 have one copy.</p> <p>17 All right. Doctor, do you remember you</p> <p>18 were asked a series of questions about</p> <p>19 cytotoxicity and degradation?</p> <p>20 A. Yes.</p> <p>21 Q. Doctor, are you aware of any randomized</p> <p>22 controlled trial that has been conducted that has</p> <p>23 determined that complications experienced</p> <p>24 postoperatively following a mesh surgery were due</p>	<p style="text-align: right;">Page 391</p> <p>1 a surgical implant, polypropylene material has</p> <p>2 been used in most surgical specialties including</p> <p>3 general surgery, cardiovascular surgery,</p> <p>4 transplant surgery, ophthalmology, oto --</p> <p>5 How do you say that word?</p> <p>6 A. Otolaryngology.</p> <p>7 Q. Thank you.</p> <p>8 "-- gynecology and urology for over</p> <p>9 5 decades in millions of patients in the U.S. and</p> <p>10 the world. As an isolated thread, polypropylene</p> <p>11 is a widely used and durable suture material</p> <p>12 employed in a broad range of sizes and</p> <p>13 applications. As a knitted material,</p> <p>14 polypropylene mesh is the consensus graft</p> <p>15 material for augmenting hernia repairs in a</p> <p>16 number of areas in the human body and has</p> <p>17 significantly and favorably impacted the field of</p> <p>18 hernia surgery. As a knitted implant for the</p> <p>19 surgical treatment of SUI, macroporous</p> <p>20 monofilament, lightweight polypropylene has</p> <p>21 demonstrated long-term durability, safety, and</p> <p>22 efficacy up to 17 years."</p> <p>23 A. Yes.</p> <p>24 Q. Did I read that correctly?</p>
<p style="text-align: right;">Page 390</p> <p>1 to either cytotoxicity or degradation?</p> <p>2 MR. RESTAINO:</p> <p>3 Objection.</p> <p>4 A. Not that I'm aware of.</p> <p>5 MR. WALKER:</p> <p>6 Q. And, Doctor, if Prolene mesh was</p> <p>7 cytotoxic or degrading to the extent that it</p> <p>8 actually would cause a clinical complication, is</p> <p>9 that the sort of thing that you would expect to</p> <p>10 see manifest quite frequently across the patient</p> <p>11 population?</p> <p>12 A. Yes.</p> <p>13 Q. And do we see that either in terms of</p> <p>14 your experience or more importantly in terms of</p> <p>15 what the medical literature says?</p> <p>16 A. The medical literature and my</p> <p>17 experience does concur with that.</p> <p>18 Q. Just to clarify, concurs that it's?</p> <p>19 A. That it's safe.</p> <p>20 Q. That it's safe?</p> <p>21 A. Yeah, and not cytotoxic.</p> <p>22 Q. And, Doctor, the AUGS/SUFU statement</p> <p>23 we've marked as Exhibit 43, it concludes:</p> <p>24 "Polypropylene material is safe and effective as</p>	<p style="text-align: right;">Page 392</p> <p>1 A. Yes, you read that correctly.</p> <p>2 Q. Do you agree with that statement?</p> <p>3 A. Yes.</p> <p>4 Q. Is that statement consistent with your</p> <p>5 clinical experience?</p> <p>6 A. Yes.</p> <p>7 Q. Is that statement consistent with what</p> <p>8 you have read in your review of the medical</p> <p>9 literature?</p> <p>10 A. Yes, that's consistent.</p> <p>11 Q. Is that the consensus position amongst</p> <p>12 the various doctors that you have interacted with</p> <p>13 and had discussions with?</p> <p>14 A. Yes.</p> <p>15 Q. What does this statement tell you in</p> <p>16 terms of the issues of cytotoxicity and</p> <p>17 degradation?</p> <p>18 A. That it is not clinically significant</p> <p>19 and that there is none reported.</p> <p>20 Q. And, Doctor, you were again asked a</p> <p>21 number of times about the 2-year benchmark that</p> <p>22 counsel opposite cited in regards to prolapse</p> <p>23 studies. Do you recall that?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 393</p> <p>1 Q. With regards to the TVT products that 2 you opine about in your report, TVT, TVT-O, 3 TVT-Abbrevio and TVT-Exact, you rely on and cite a 4 number of long-term studies; correct? 5 A. Yes. 6 Q. And I don't recall the exact number, 7 but there are around -- well, strike that. 8 You would agree that there are several 9 5 to 10, and sometimes even longer than 10-year 10 follow-up studies that have looked at both TVT 11 retropubic and TVT obturator; correct? 12 A. Yes. 13 Q. And your review of those studies -- in 14 your review of those studies -- strike that. 15 Does your review of those studies 16 support your opinion concerning the safety and 17 efficacy of those products? 18 A. Yes. 19 Q. Doctor, are all of the opinions 20 contained in your TVT general report -- that 21 again covers TVT retropubic, TVT obturator, 22 TVT-Abbrevio and TVT-Exact -- 23 A. Correct. 24 Q. -- are all of those opinions held by</p>	<p style="text-align: right;">Page 395</p> <p>1 says here over -- importantly -- over three 2 million midurethral slings have been placed 3 worldwide and a recent survey indicates that the 4 procedure is used by greater than 99 percent of 5 AUGS members. 6 Q. And why is that important to you? 7 A. Just because this is the treatment for 8 stress incontinence by 99 percent of AUGS 9 members. It's the recommendation that -- 10 midurethral slings are the recommendation for 11 treatment for stress incontinence. That's all. 12 EXAMINATION 13 BY MR. RESTAINO: 14 Q. Doctor, I've got just a few follow-up 15 questions. 16 A. No problem. 17 Q. Number one pertaining to the statement 18 you just made with the -- the number that you 19 just quoted. That does not rule out the fact 20 that a percentage of women have adverse events 21 and serious adverse events secondary to the mesh; 22 correct? 23 A. It does not address that. 24 Q. You can pull it -- obviously, you can</p>
<p style="text-align: right;">Page 394</p> <p>1 you to a reasonable degree of medical certainty? 2 A. Yes. 3 Q. And are those opinions based on your 4 education, your training, your experience, your 5 review of the medical literature, and your 6 discussions with your colleagues? 7 A. Yes. As well as recommendations from 8 our societies. 9 MR. WALKER: 10 That's all I have. Thank you. 11 A. Can I just say one thing about this 12 AUGS report? 13 MR. WALKER: 14 Q. Do you want it on or off the record? 15 A. I was going to say, can I put it on the 16 record? 17 Q. Yeah. 18 A. Just from -- from this -- this Position 19 Statement, for someone like myself that's in the 20 trenches, seeing patients, and it reports here in 21 the -- polypropylene mesh midurethral slings are 22 a standard of care for the surgical treatment of 23 SUI and represent a great advance in the 24 treatment of this condition for our patients. It</p>	<p style="text-align: right;">Page 396</p> <p>1 pull it if you would like, but you were asked 2 about the Klinge study, and you were -- if you 3 look on the -- if you look on the second page 4 under material and methods -- 5 A. Okay. Yes. 6 Q. -- in the right column, at the top, you 7 read -- it was read: "Except for one Marlex mesh 8 with a fistula to the intestine, no mesh showed 9 macroscopic signs of infection or inflammation"; 10 correct? 11 A. Correct. 12 Q. Can you define for the Court 13 macroscopic? 14 A. When they looked at it under the 15 microscope, the pathologist looked at it under 16 the microscope. Macroscopic. Excuse me. I'm so 17 sorry. Macroscopic means visual sight. Sorry. I 18 read that as microscopic. 19 Q. So the fact that there weren't 20 macroscopic signs of infection or inflammation 21 does not rule out the fact that there may have 22 been microscopic signs of infection and infection 23 and inflammation including white blood cells, 24 bacteria, macrophages, giant cells, all of that;</p>

<p style="text-align: right;">Page 397</p> <p>1 correct?</p> <p>2 A. You would only be able to see that</p> <p>3 under the microscope.</p> <p>4 Q. Okay. And then I haven't had a chance</p> <p>5 to see the articles that you brought today. But</p> <p>6 if we can turn to -- if you would turn to the</p> <p>7 Holdo study.</p> <p>8 A. Holdo, yes.</p> <p>9 MR. WALKER:</p> <p>10 Where did it go? Hang on. Here it is.</p> <p>11 Here it is. Did you want to look at it first?</p> <p>12 MR. RESTAINO:</p> <p>13 Q. I brought that one up on PubMed.</p> <p>14 A. What you got?</p> <p>15 Q. If you'd go to the 6th page, which is</p> <p>16 listed here just as page 6. I don't see a page</p> <p>17 number on it. It's the 6th page, and then on the</p> <p>18 lower right-hand column down below, it says</p> <p>19 strengths and weaknesses.</p> <p>20 A. Strengths and weaknesses.</p> <p>21 Q. Okay. Good.</p> <p>22 "The strengths and weaknesses of this</p> <p>23 study should be considered. In this</p> <p>24 retrospective study, data were not collected</p>	<p style="text-align: right;">Page 399</p> <p>1 Q. Why would mesh be removed otherwise?</p> <p>2 A. No. Just -- it wouldn't be, yes, sir.</p> <p>3 Q. So urological, gynecologic surgeons</p> <p>4 don't take mesh out of healthy people; correct?</p> <p>5 A. Correct.</p> <p>6 MR. RESTAINO:</p> <p>7 Okay. That's all I have.</p> <p>8 MR. WALKER:</p> <p>9 We are good.</p> <p>10 (THE DEPOSITION OF MARSHALL SHOEMAKER,</p> <p>11 M.D., WAS CONCLUDED AT 11:09 A.M.)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 398</p> <p>1 systematically as in prospective studies, and the</p> <p>2 recorded data were those documented in the</p> <p>3 medical records. Grading of symptoms and</p> <p>4 complaints were based on the patients' subjective</p> <p>5 descriptions and the data needs to be interpreted</p> <p>6 with caution as they may vary in quality and</p> <p>7 consistency."</p> <p>8 Do you agree with that statement?</p> <p>9 A. This statement is -- I agree that the</p> <p>10 statement is in here, yeah.</p> <p>11 Q. Okay. Would you agree that in any or</p> <p>12 in all retrospective studies where the recorded</p> <p>13 data is only obtained from medical records, that</p> <p>14 that data has to be interpreted with caution</p> <p>15 because it may vary in quality and consistency?</p> <p>16 A. It can be -- it can be difficult.</p> <p>17 Q. Okay. You were asked about the</p> <p>18 Burbaker?</p> <p>19 A. Brubaker.</p> <p>20 Q. That one too.</p> <p>21 The Brubaker study, and counsel pointed</p> <p>22 out that all the mesh were removed from patients</p> <p>23 with complaints; correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 400</p> <p>1 C E R T I F I C A T E</p> <p>2 I do hereby certify that the foregoing</p> <p>3 proceedings were taken down by me and transcribed</p> <p>4 using computer-aided transcription and that the</p> <p>5 foregoing is a true and correct transcript of</p> <p>6 said proceedings.</p> <p>7 I further certify that I am neither of</p> <p>8 counsel nor of kin to any of the parties, nor am</p> <p>9 I in anywise interested in the result of said</p> <p>10 cause.</p> <p>11 I further certify that I am licensed by</p> <p>12 the Alabama Board of Court Reporting as a</p> <p>13 Certified Court Reporter.</p> <p>14</p> <p>15</p> <p>16 _____</p> <p>17 LYNN ROBINSON-DYKES, CCR</p> <p>18 ACCR#175 (exp. 9/30/17)</p> <p>19 COURT REPORTER, NOTARY PUBLIC (exp. 1/29/2020)</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>



Marshall Shoemaker, M.D.

Page 401

1 CERTIFICATE OF WITNESS  
2 ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS  
3 LIABILITY LITIGATION 2:12-M-02327  
4  
5 I, MARSHALL SHOEMAKER, M.D., do hereby  
6 certify that on this \_\_\_\_ day of \_\_\_\_\_,  
7 2017, I have read the transcript and to the best  
8 of my knowledge it constitutes a true and  
9 accurate transcript of my testimony taken on oral  
10 examination on July 22, 2017.  
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\_\_\_\_\_  
MARSHALL SHOEMAKER, M.D.

DATE: \_\_\_\_\_

\_\_\_\_\_  
WITNESS TO SIGNATURE

Page 403

1 CERTIFICATE OF CHANGE  
2 ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS  
3 LIABILITY LITIGATION 2:12-M-0227  
4 I, MARSHALL SHOEMAKER, M.D., the  
5 witness, have read the testimony contained herein  
6 and hereby request the following changes be made:  
7 PAGE/LINE CHANGE TO  
8 \_\_\_\_\_  
9 \_\_\_\_\_  
10 \_\_\_\_\_  
11 \_\_\_\_\_  
12 \_\_\_\_\_  
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19 Subscribed and sworn to before me this \_\_\_\_ day  
20 of \_\_\_\_\_ 20\_\_\_\_.  
21 My Commission Expires:  
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MARSHALL SHOEMAKER, M.D.

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NOTARY PUBLIC

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1 CERTIFICATE OF CHANGE  
2 ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS  
3 LIABILITY LITIGATION 2:12-M-0227  
4 I, MARSHALL SHOEMAKER, M.D., the  
5 witness, have read the testimony contained herein  
6 and hereby request the following changes be made:  
7 PAGE/LINE CHANGE TO  
8 \_\_\_\_\_  
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20 Subscribed and sworn to before me this \_\_\_\_ day  
21 of \_\_\_\_\_ 20\_\_\_\_.  
22 My Commission Expires:  
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MARSHALL SHOEMAKER, M.D.

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